



# STIC Search Report

## EIC 3700

STIC Database Tracking Number: 134692

TO: Andrea Ragonese  
Location: pk1 11e50  
Art Unit: 3743  
Tuesday, October 12, 2004

Case Serial Number: 10/079604

From: Emory Damron  
Location: EIC 3700  
CP2-2C08  
Phone: 305-8587

Emory.Damron@uspto.gov

### Search Notes

Dear Andrea,

Please find below an inventor search in the bibliographic and full-text foreign patent files, as well as keyword searches in the patent and non-patent literature files, both bibliographic and full text.

References of potential pertinence have not been tagged (per your request), so please review all the packets carefully.

Please note any manual highlighting which I've done within the document.

In addition to searching on Dialog, I also searched EPO/JPO/Derwent.

Please contact me if I can refocus or expand any aspect of this case, and please take a moment to provide any feedback (on the form provided) so EIC 3700 may better serve your needs.

Sincerely,  
Emory Damron  
Technical Information Specialist  
EIC 3700, US Patent & Trademark Office  
Phone: (703) 305-8587/ Fax: (703) 306-5915  
Emory.damron@uspto.gov



134692

## SEARCH REQUEST FORM

## Scientific and Technical Information Center

Requester's Full Name: ANDREA RAGONESE Examiner #: 77465 Date: 10/7/2004  
Art Unit: 3743 Phone Number 306-4055 Serial Number: 10 079 604  
Mail Box and Bldg/Room Location: PK 1 HESD Results Format Preferred (circle): PAPER DISK E-MAIL

If more than one search is submitted, please prioritize searches in order of need.

\*\*\*\*\*

Please provide a detailed statement of the search topic, and describe as specifically as possible the subject matter to be searched. Include the elected species or structures, keywords, synonyms, acronyms, and registry numbers, and combine with the concept or utility of the invention. Define any terms that may have a special meaning. Give examples or relevant citations, authors, etc, if known. Please attach a copy of the cover sheet, pertinent claims, and abstract.

Title of Invention: CLEARING MODES OF OPERATION OF MEDICAL ENGINEERING DEVICES

Inventors (please provide full names): KRUGER, THOMAS ; SCHMIDT, HARTMUT ;  
WAHLE, HANS-GEORG

Earliest Priority Filing Date: 4 APRIL 2001

\*For Sequence Searches Only\* Please include all pertinent information (parent, child, divisional, or issued patent numbers) along with the appropriate serial number.

See attached

PG PUB : 2002/0144682

## STAFF USE ONLY

	Type of Search	Vendors and cost where applicable
Searcher: <u>EMILY DAMRON</u>	NA Sequence (#) _____	STN _____
Searcher Phone #: <u>305 5587</u>	AA Sequence (#) _____	Dialog <u>X</u> <u>164760</u>
Searcher Location: <u>CPE 258</u>	Structure (#) _____	Questel/Orbit _____
Date Searcher Picked Up: <u>10/8/04</u>	Bibliographic <u>X</u>	Dr.Link _____
Date Completed: <u>10/12/04</u>	Litigation _____	Lexis/Nexis _____
Searcher Prep & Review Time: <u>300m</u>	Fulltext <u>X</u>	Sequence Systems _____
Clerical Prep Time: <u>300m</u>	Patent Family _____	WWW/Internet _____
Online Time: _____	Other _____	Other (specify) _____

Set	Items	Description
S1	2658	AU=(KRUGER T? OR KRUGER, T? OR SCHMIDT H? OR SCHMIDT, H? OR WAHLE H? OR WAHLE, H? OR WAHLE G? OR WAHLE, G?)
S2	0	(TOM OR THOMAS) (2N) KRUGER OR HARTMUT (2N) SCHMIDT OR (HANS OR GEORG?) (2N) WAHLE
S3	151804	RESPIR? OR BREATH? OR VENTILAT? OR BREATH? OR CPAP OR PEEP OR IPAP
S4	471282	IC=(A62B? OR A61M? OR F16K? OR A61B?)
S5	108	S1:S2 AND S3:S4
S6	31	S5 AND S3
S7	31	IDPAT (sorted in duplicate/non-duplicate order)

? show files

File 347:JAPIO Nov 1976-2004/Jun(Updated 041004)

(c) 2004 JPO & JAPIO

File 350:Derwent WPIX 1963-2004/UD,UM &UP=200464

(c) 2004 Thomson Derwent

INVENTOR - AUTHOR SEARCH
PATLIT & NONPATLIT
SELECTED EDITED HITS <del>OTHER HITS</del>

7/3,K/10 (Item 10 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

*THE APPLICATION*

015031046 \*\*Image available\*\*  
WPI Acc No: 2003-091563/200308  
XRPX Acc No: N03-072498

Respirator operation mode clearance method involves determining  
clearance of available respiration modes on respirator , based on data  
read from chip card by writing/reading unit

Patent Assignee: DRAEGER MEDICAL & CO AG KGAA (DRAE-N); DRAGER MEDICAL & CO  
AG KGAA (DRAG-N); KRUGER T (KRUG-I); SCHMIDT H (SCHM-I); WAHLE H (WAHL-I)

Inventor: KRUEGER T; SCHMIDT H ; WAHLE H ; KRUGER T ; WAHLE H G

Number of Countries: 003 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20020144682	A1	20021010	US 200279604	A	20020220	200308 B
FR 2823121	A1	20021011	FR 20024149	A	20020403	200308
DE 10116650	A1	20021107	DE 1016650	A	20010404	200308

Priority Applications (No Type Date): DE 1016650 A 20010404

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

US 20020144682 A1 7 A62B-007/00

FR 2823121 A1 A61M-016/00

DE 10116650 A1 A61B-019/00

Respirator operation mode clearance method involves determining  
clearance of available respiration modes on respirator , based on data  
read from chip card by writing/reading unit

...Inventor: SCHMIDT H ...

... WAHLE H ...

... KRUGER T ...

... WAHLE H G

Abstract (Basic):

... The data specifying different available respiration modes on  
the respirator , are read from a chip card (2) by a writing/reading  
unit (3). The cleaning of the respiration modes is determined, based  
on the data read by the writing/reading unit.

... An INDEPENDENT CLAIM is included for respirator system...

...For cleaning mode of operations such as intermittent mandatory  
ventilation (IMV), continuous positive airway pressure ( CPAP ) and  
high-frequency ventilation (HFV) on respirator .

...

...Enables the respiration modes on the respirator to be changed  
without great technical effort...

...The figure shows a schematic view of the respirator .

Title Terms: RESPIRATION ;

International Patent Class (Main): A61B-019/00 ...

... A61M-016/00 ...

... A62B-007/00



7/3,K/27 (Item 27 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

004068431

WPI Acc No: 1984-213972/198435

XRPX Acc No: N84-160199

Dry cold air stream producer - has liquid nitrogen source which mixes  
with filtered air flow

Patent Assignee: MESSER GRIESHEIM GMBH (MESG )

Inventor: JANKOWSKI D; SCHMIDT H ; THOMA K; VOLKER W; VONDERBEY T

Number of Countries: 009 Number of Patents: 006

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
DE 3305434	A	19840823	DE 3305434	A	19830217	198435 B
EP 116834	A	19840829	EP 84100220	A	19840111	198435
NO 8400333	A	19840910				198443
US 4532779	A	19850806	US 84573838	A	19840125	198534
DE 3305434	C	19851128				198549
EP 116834	B	19860528				198622

Priority Applications (No Type Date): DE 3305434 A 19830217

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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DE 3305434	A		10		
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EP 116834	A	G			
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Designated States (Regional): AT BE FR GB NL SE

EP 116834	B	G			
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Designated States (Regional): AT BE FR GB NL SE

...Inventor: SCHMIDT H

...Abstract (Basic): are attached. A temp. sensor (21) is located near the  
hand piece. A spent air ventilator (22) is situated near by which  
runs while the machine is switched on. An oxygen...

*see beneath*

Set	Items	Description
S1	16723	(VENTILAT? OR RESPIRAT? OR BREATH?) (3N) (DEVICE? OR UTENSIL? OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN- C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2	39245	VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR HFV OR IMV OR IPAP OR CPAV OR PEEP OR CPAP
S3	1930912	CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE- T? OR OVERRID? OR OVERWIT? OR OVER() (RIDE? OR RIDING OR WRIT- ?) OR REPROGRAM? OR REMOV?
S4	6047087	OPERAT? OR FUNCTION? OR PERFORMANC? OR WORKING? OR EXECUTI? OR DATA? OR PROGRAM?
S5	152811	(READ? OR SCAN? OR DECOD?) (5N) (WRIT? OR CODE? OR CODING? OR CODIF?)
S6	11821	(CHIP? OR SMART? OR DEBIT? OR PROGRAMABL? OR PROGRAMMABL?) - (3N)CARD? OR SMARTCARD? OR CHIPCARD?
S7	268323	(STORE? OR STORING? OR STORAGE) (3N) (DEVICE? OR MEDIUM? OR - ELECTRONIC? OR OPTIC? OR MAGNET?)
S8	1019446	CACHE? OR MEMORY? OR RAM OR (EXTERNAL OR REMOVABL? OR DETA- CHABL? OR STANDALONE OR STAND()ALONE OR PORTABL OR INSERTABL?- ) (2N) (UNIT? OR DEVICE?)
S9	809193	CPU OR CPUS OR PROGRAM?()CONTROL? OR PROCESS?(2N)CONTROL? - OR MICROPROCESS? OR DATAPROCESS? OR CENTRALPROCESS? OR (MICRO OR DATA OR CENTRAL) ()PROCESS?
S10	251554	PROCESS?()UNIT? OR WORKSTATION? OR WORK()STATION? OR DESKT- OP? OR DESK() (TOP OR TOPS) OR SERVER?
S11	785241	COMPUTER OR COMPUTERS OR PC OR PCS
S12	4273140	METHOD? ?
S13	3086734	SYSTEM? ?
S14	2498531	PROCESS??
S15	204660	PROCEDUR?
S16	227816	TECHNIQU?
S17	493577	MODE? ?
S18	471282	IC=(A62B? OR A61M? OR F16K? OR A61B?)
S19	9383	S1:S2 AND S18
S20	52418	S19 OR S1:S2
S21	2043	S20 AND S6:S8
S22	1954	S20 AND S9:S11
S23	257	S21 AND S22
S24	3740	S21:S22
S25	74	S24 AND S3(5N)S4:S8
S26	4	S23 AND S25
S27	74	S25:S26
S28	201	S23 AND S12:S17
S29	74	S28 AND S18
S30	147	S27 OR S29
S31	147	IDPAT (sorted in duplicate/non-duplicate order)

? show files

File 347:JAPIO Nov 1976-2004/Jun(Updated 041004)

(c) 2004 JPO & JAPIO

File 350:Derwent WPIX 1963-2004/UD,UM &UP=200464

(c) 2004 Thomson Derwent

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31/3,K/12 (Item 12 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

016309417 \*\*Image available\*\*

WPI Acc No: 2004-467312/200444

Related WPI Acc No: 1994-134983; 1995-383132; 1996-496747; 1997-525383;  
1998-168289; 1998-251468; 1998-426808; 1998-456711; 1998-568188;  
1999-228839; 1999-242495; 1999-287122; 1999-302397; 1999-311681;  
1999-384097; 1999-405126; 1999-417667; 1999-507606; 1999-526845;  
1999-539738; 1999-561252; 2000-012778; 2000-061786; 2000-181692;  
2000-195149; 2000-328448; 2000-338806; 2000-338807; 2000-338954;  
2000-423081; 2000-431044; 2000-474547; 2000-498702; 2000-571401;  
2000-593531; 2000-655125; 2001-210131; 2001-225710; 2001-307032;  
2001-307130; 2001-407641; 2001-513222; 2001-564621; 2001-578438;  
2001-579931; 2001-611417; 2001-624850; 2002-112617; 2002-121382;  
2002-170531; 2002-215991; 2002-327599; 2002-360451; 2002-415808;  
2002-416321; 2002-433601; 2002-453253; 2002-470164; 2002-527573;  
2002-617729; 2003-074907; 2003-657592; 2004-009535; 2004-131367;  
2004-202085; 2004-460441; 2004-467342; 2004-498375; 2004-498376;  
2004-498377

XRPX Acc No: N04-369203

Airflow monitoring system for chronic respiratory affliction, has  
health care professional computer that is in signal communication with  
clearing house receives health-related information based on  
airflow-related data

Patent Assignee: HEALTH HERO NETWORK INC (HEAL-N)

Inventor: BROWN S J

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20040106855	A1	20040603	US 92977323	A	19921117	200444 B
			US 94233397	A	19940426	
			US 95481925	A	19950607	
			US 99237194	A	19990126	
			US 2003605547	A	20031007	

Priority Applications (No Type Date): US 92977323 A 19921117; US 94233397 A  
19940426; US 95481925 A 19950607; US 99237194 A 19990126; US 2003605547 A  
20031007

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 20040106855	A1	21	G06F-017/60	Cont of application US 92977323 Cont of application US 94233397 Cont of application US 95481925 Cont of application US 99237194 Cont of patent US 5307263 Cont of patent US 5899855

Airflow monitoring system for chronic respiratory affliction, has  
health care professional computer that is in signal communication with  
clearing house receives health-related information based on airflow...

Abstract (Basic):

... The system has a clearing house (54) that receives and  
communicates data. A microprocessor -based unit (12) with a  
microprocessor, display and a memory is arranged to communicate  
airflow related data to the server. A health care professional  
computer in signal communication with the house receives  
health-related information based on the airflow-related...

... An INDEPENDENT CLAIM is also included for an airflow monitoring  
method .

...

...Used for self-care monitoring and control of afflictions and physical  
conditions e.g. chronic **respiratory** afflictions...

...The **system** enables healthcare professional to review the data and  
record it for latter user to perform...

...The drawing shows a block diagram depicting a healthcare monitoring  
**system** .

...

... **Microprocessor** -based unit (12

...Title Terms: **SYSTEM** ;

International Patent Class (Additional): **A61B-005/00**

31/3,K/37 (Item 37 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

015161090 \*\*Image available\*\*  
WPI Acc No: 2003-221618/200321  
XRAM Acc No: C03-056389  
XRPX Acc No: N03-176785

General purpose modular sensor unit for portable health monitor,  
comprises application software for controlling intelligent processor  
and control layer which processes data output from sensor array layer  
Patent Assignee: BATTELLE MEMORIAL INST (BATT ); GRIFFIN J W (GRIF-I);  
LIND M A (LIND-I); MORGAN G B (MORG-I); PRIDDY K L (PRID-I); RIDGWAY R W  
(RIDG-I); STEIN S L (STEI-I)  
Inventor: GRIFFIN J W; LIND M A; MORGAN G B; PRIDDY K L; RIDGWAY R W; STEIN  
S L

Number of Countries: 101 Number of Patents: 004

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200304975	A1	20030116	WO 2002US20908	A	20020702	200321 B
US 20030033032	A1	20030213	US 2001302563	P	20010702	200321
			US 2002188469	A	20020702	
EP 1405044	A1	20040407	EP 2002742377	A	20020702	200425
			WO 2002US20908	A	20020702	
AU 2002315514	A1	20030121	AU 2002315514	A	20020702	200452

Priority Applications (No Type Date): US 2001302563 P 20010702; US  
2002188469 A 20020702

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200304975 A1 E 51 G01D-021/02

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN  
IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ  
OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU  
ZA ZM ZW

Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB  
GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW

US 20030033032 A1 G05B-011/01 Provisional application US 2001302563

EP 1405044 A1 E G01D-021/02 Based on patent WO 200304975

Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB  
GR IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR

AU 2002315514 A1 G01D-021/02 Based on patent WO 200304975

General purpose modular sensor unit for portable health monitor,  
comprises application software for controlling intelligent processor  
and control layer which processes data output from sensor array layer

Abstract (Basic):

... The general purpose intelligent processor and control layers  
comprises reprogrammable memory which stores application specific  
software to control the operation of these layers, which process  
conditioned...

...output from sensor array layer. A power layer supplies power to the  
sensor array layer, processor and control layers. The processor  
power, array and control layers are arranged to form a sensor module.  
... medicine, biological threat detection and/or non-invasive blood  
chemistry testing, drug efficacy monitoring, medical ventilator

monitoring, crop health monitor and/or smart patch medical emergency  
diagnostics, etc...

31/3,K/38 (Item 38 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

015150236 \*\*Image available\*\*  
WPI Acc No: 2003-210763/200320  
XRPX Acc No: N03-167919

Ventilator has embedded web server which can be connected to  
external monitoring devices and can be operated from mains power or  
external battery

Patent Assignee: EVENT MEDICAL LTD (EVEN-N); IMT MEDICAL AG (IMTM-N)

Inventor: DASCHER J; GRIFFITHS M; DAESCHER J

Number of Countries: 097 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200313635	A1	20030220	WO 2001IB1362	A	20010730	200320 B
EP 1414509	A1	20040506	EP 2001956725	A	20010730	200430
			WO 2001IB1362	A	20010730	
AU 2001278642	A1	20030224	AU 2001278642	A	20010730	200460
			WO 2001IB1362	A	20010730	

Priority Applications (No Type Date): WO 2001IB1362 A 20010730

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200313635 A1 E 14 A61M-016/00

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA  
CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN  
IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ  
PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW

Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR  
IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW

EP 1414509 A1 E A61M-016/00 Based on patent WO 200313635

Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT  
LI LT LU LV MC MK NL PT RO SE SI TR

AU 2001278642 A1 A61M-016/00 Based on patent WO 200313635

Ventilator has embedded web server which can be connected to  
external monitoring devices and can be operated from mains power or  
external battery

Abstract (Basic):

... The ventilator has a housing (7) with gas connections (1).  
There is a controlled valve (2), a...

...compressor (6) and at least one patient connection (12). At least one of  
the control systems (2,4 or 8) is connected to an embedded web  
server (5) which provides a connection to one external monitor (13)  
via at least one data...

... Control systems (4,8...

International Patent Class (Main): A61M-016/00

31/3,K/40 (Item 40 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

*THIS APPLICATION*

015031046 \*\*Image available\*\*  
WPI Acc No: 2003-091563/200308  
XRPX Acc No: N03-072498

Respirator operation mode clearance method involves determining  
clearance of available respiration modes on respirator , based on data  
read from chip card by writing/reading unit

Patent Assignee: DRAEGER MEDICAL & CO AG KGAA (DRAE-N); DRAGER MEDICAL & CO  
AG KGAA (DRAG-N); KRUGER T (KRUG-I); SCHMIDT H (SCHM-I); WAHLE H (WAHL-I)  
Inventor: KRUEGER T; SCHMIDT H; WAHLE H; KRUGER T; WAHLE H G  
Number of Countries: 003 Number of Patents: 003  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20020144682	A1	20021010	US 200279604	A	20020220	200308 B
FR 2823121	A1	20021011	FR 20024149	A	20020403	200308
DE 10116650	A1	20021107	DE 1016650	A	20010404	200308

Priority Applications (No Type Date): DE 1016650 A 20010404

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 20020144682	A1		7 A62B-007/00	
FR 2823121	A1		A61M-016/00	
DE 10116650	A1		A61B-019/00	

Respirator operation mode clearance method involves determining  
clearance of available respiration modes on respirator , based on data  
read from chip card by writing/reading unit

Abstract (Basic):

... The data specifying different available respiration modes on the  
**respirator** , are read from a **chip card** (2) by a writing/reading  
unit (3). The cleaning of the respiration modes is determined...  
... An INDEPENDENT CLAIM is included for **respirator** system...

...For cleaning mode of operations such as intermittent mandatory  
ventilation ( **IMV** ), continuous positive airway pressure ( **CPAP** ) and  
high-frequency ventilation ( **HFV** ) on **respirator** .  
...

...Enables the respiration modes on the **respirator** to be changed without  
great technical effort...

...The figure shows a schematic view of the **respirator** .  
...

... **Chip card** (2

International Patent Class (Main): **A61B-019/00** ...

... **A61M-016/00** ...

... **A62B-007/00**



31/3,K/49 (Item 49 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

014573514 \*\*Image available\*\*  
WPI Acc No: 2002-394218/200242  
XRPX Acc No: N02-309083

Breathing gas delivery system has microprocessor calculating excess leak, tidal profile and peak flow using measured flow rate and purge hole leak profile

Patent Assignee: MALLINCKRODT INC (MLCW )  
Inventor: BONNETTE B J; EMERSON P F; HANSEN G L  
Number of Countries: 029 Number of Patents: 004  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200226304	A2	20020404	WO 2001US30456	A	20010928	200242 B
US 6546930	B1	20030415	US 2000672955	A	20000929	200329
EP 1322368	A2	20030702	EP 2001979321	A	20010928	200344
			WO 2001US30456	A	20010928	
JP 2004509710	W	20040402	WO 2001US30456	A	20010928	200424
			JP 2002530133	A	20010928	

Priority Applications (No Type Date): US 2000672955 A 20000929

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200226304	A2	E	26	A61M-016/00	
				Designated States (National):	CA JP
				Designated States (Regional):	AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
US 6546930	B1			A61M-016/00	
EP 1322368	A2	E		A61M-016/00	Based on patent WO 200226304
				Designated States (Regional):	AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR
JP 2004509710	W		71	A61M-016/00	Based on patent WO 200226304

Breathing gas delivery system has microprocessor calculating excess leak, tidal profile and peak flow using measured flow rate and purge hole

...

Abstract (Basic):

... **System** comprises a blower with a gas flow rate sensor and a **memory** containing purge hole leak profiles corresponding to specific types of **breathing appliances**. A **microprocessor** calculates excess leak, tidal volume and peak flow using the measured flow rate and the

... There is an INDEPENDENT CLAIM for a **method** of delivering a breathing gas to a patient...

... **System** is for use in treating sleep apnea...

...The figure shows the breathing gas delivery **system**.

...Title Terms: **SYSTEM** ;

International Patent Class (Main): **A61M-016/00**

International Patent Class (Additional): **A62B-007/00** ...

... **F16K-031/02**

31/3,K/50 (Item 50 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

014496531 \*\*Image available\*\*  
WPI Acc No: 2002-317234/200236  
XRPX Acc No: N02-248371

User interface for use with medical apparatus e.g. medical ventilator  
, has controller to process normal and signal data and show signal  
data as sector in regular polygon on display screen

Patent Assignee: SIEMENS-ELEMA AB (SIEI )

Inventor: MALMBORG J

Number of Countries: 028 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 1178288	A1	20020206	EP 2001114238	A	20010612	200236 B
US 20020015034	A1	20020207	US 2001919105	A	20010731	200236
JP 2002153429	A	20020528	JP 2001234104	A	20010801	200238

Priority Applications (No Type Date): SE 20002806 A 20000801

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

EP 1178288 A1 E 13 G01D-007/02

Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT  
LI LT LU LV MC MK NL PT RO SE SI TR

US 20020015034 A1 G09G-005/00

JP 2002153429 A 9 A61B-005/00

User interface for use with medical apparatus e.g. medical ventilator  
, has controller to process normal and signal data and show signal  
data as sector in regular polygon on display...

Abstract (Basic):

... A controller (18) processes normal data for two or more  
parameters, as well as the signal data for the...

... An input unit (20) introduces the signal data into the  
controller. A memory (14) stores the normal data. The regular polygon  
corresponds to the representation...

...For displaying physiological or apparatus-related parameters, and for  
use with medical apparatus e.g. medical ventilator .

...

... Memory (14

...Title Terms: PROCESS ;

International Patent Class (Main): A61B-005/00 ...

International Patent Class (Additional): A61B-005/02 ...'

... A61M-016/00

31/3,K/55 (Item 55 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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014127175 \*\*Image available\*\*

WPI Acc No: 2001-611385/200170

XRAM Acc No: C01-182649

XRPX Acc No: N01-456382

Dry powder inhaler for nasal and/or oral respiratory delivery of dry powder-based drug formulations, is provided with control system comprising controller, power source, transformer, and computer -readable program code

Patent Assignee: UNIV NORTH CAROLINA (UYNC-N); CROWDER T M (CROW-I); HICKEY A J (HICK-I)

Inventor: CROWDER T M; HICKEY A J

Number of Countries: 095 Number of Patents: 010

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200168169	A1	20010920	WO 2001US2262	A	20010124	200170	B
AU 200131102	A	20010924	AU 200131102	A	20010124	200208	
NO 200204311	A	20021111	WO 2001US2262	A	20010124	200304	
			NO 20024311	A	20020909		
EP 1267969	A1	20030102	EP 2001903260	A	20010124	200310	
			WO 2001US2262	A	20010124		
KR 2002086624	A	20021118	KR 2002711799	A	20020909	200320	
BR 200109127	A	20030422	BR 20019127	A	20010124	200330	
			WO 2001US2262	A	20010124		
CN 1416357	A	20030507	CN 2001806260	A	20010124	200353	
JP 2003526480	W	20030909	JP 2001566730	A	20010124	200360	
			WO 2001US2262	A	20010124		
MX 2002008605	A1	20030501	WO 2001US2262	A	20010124	200415	
			MX 20028605	A	20020903		
US 20040123864	A1	20040701	WO 2001US2262	A	20010124	200444	
			US 2003204609	A	20030129		

Priority Applications (No Type Date): US 2000188543 P 20000310; US 2003204609 A 20030129

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

WO 200168169 A1 E 71 A61M-015/00  
Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW  
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW  
AU 200131102 A A61M-015/00 Based on patent WO 200168169  
NO 200204311 A A61M-000/00  
EP 1267969 A1 E A61M-015/00 Based on patent WO 200168169  
Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR  
KR 2002086624 A A61M-015/00  
BR 200109127 A A61M-015/00 Based on patent WO 200168169  
CN 1416357 A A61M-015/00  
JP 2003526480 W 72 A61M-015/00 Based on patent WO 200168169  
MX 2002008605 A1 A61M-015/00 Based on patent WO 200168169  
US 20040123864 A1 A61M-015/00

Dry powder inhaler for nasal and/or oral respiratory delivery of dry powder-based drug formulations, is provided with control system comprising controller, power source, transformer, and computer -readable

**program code**

**Abstract (Basic):**

... A dry powder inhaler having an active energy-assisted dispersing **system** is constructed with a housing for receiving a multi-dose dry powder package; and a control **system** positioned in the housing and comprising a controller, a power source, a transformer, and a **computer** -readable program code.

... A dry powder inhaler (10) having an active energy-assisted dispersing **system**, is provided with a control **system** and a housing. The housing receives a multi-dose dry powder package and includes an airstream exit flow path. The control **system** is positioned in the housing and comprises a controller, a power source, a transformer, and a **computer** -readable program code. The power source generates excitation energy directed to a selected region of...

...B) a **method** of dispersing a predetermined quantity of dry powder pharmaceutical drug to a patient's airstream...

...C) a **method** of controlling the dry powder inhaler...

...D) a **method** of fabricating a multi-dose dry powder package; and...

...E) a **computer** program product for directing the operation of the dry powder inhaler...

...administration of the dry powder drug and adjusting the energy directed to the active delivery **system**. The **computer** program product comprises a **computer** -readable **storage medium** having **computer** -readable program code embodied in the medium. The **computer** -readable program code includes program codes for respectively...

...ii) defining a fuzzy logic analysis **model** to control the amount of energy delivered to the active delivery **system** ;  
(...

...the type, frequency, and/or size of the excitation signal directed to the active energy **system** of the inhaler...

...For nasal and/or oral **respiratory** delivery of dry powder-based drug formulations

**Technology Focus:**

... a disposable multi-dose dry powder package having spatially-separated dry powder drug doses. The **computer** -readable program code establishes a fuzzy logic **model** of the flowability of the dry powder formulation, which is administered, and an associated excitation...

...Title Terms: **SYSTEM** ;

International Patent Class (Main): **A61M-000/00** ...

... **A61M-015/00**

International Patent Class (Additional): **A61M-013/00**

31/3,K/60 (Item 60 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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013684080 \*\*Image available\*\*  
WPI Acc No: 2001-168304/200117  
XRAM Acc No: C01-050171  
XRPX Acc No: N01-121406

Ventilator comprises ventilator setting control(s), sensors, a processing subsystem, and a feedback system responsive to the response signal of the processing subsystem

Patent Assignee: UNIV FLORIDA (UYFL ); BANNER M J (BANN-I); BLANCH P B (BLAN-I); EULIANO N R (EULI-I); PRINCIPE J C (PRIN-I)

Inventor: BANNER M J; BLANCH P B; EULIANO N R; PRINCIPE J C

Number of Countries: 022 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200100265	A1	20010104	WO 2000US18195	A	20000630	200117 B
AU 200060645	A	20010131	AU 200060645	A	20000630	200124
US 20040003813	A1	20040108	US 99141676	P	19990630	200404
			US 2000607713	A	20000630	
			US 2003407160	A	20030404	

Priority Applications (No Type Date): US 99141676 P 19990630; US 2000607713 A 20000630; US 2003407160 A 20030404

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200100265	A1	E	55	A61M-016/00	
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Designated States (National): AU CA JP

Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

AU 200060645	A				
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Based on patent WO 200100265

US 20040003813	A1			A61M-016/00	Provisional application US 99141676
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Cont of application US 2000607713

Ventilator comprises ventilator setting control(s), sensors, a processing subsystem, and a feedback system responsive to the response signal of the processing subsystem

Abstract (Basic):

... A ventilator comprises ventilator setting control(s); sensors for measuring ventilation support parameters; a processing subsystem connected to receive the output signals from the sensors and the ventilator setting parameter signal from the ventilator setting control; and a feed back system responsive to the response signal of the processing subsystem.

... A ventilator (20) comprises ventilator setting control(s); sensors (52) for measuring ventilation support parameters; a processing subsystem connected to receive the output signals from the sensors and the ventilator setting parameter signal from the ventilator setting control; and a feed back system responsive to the response signal of the processing subsystem. The ventilator setting control governs the supply of ventilation support from the ventilator to the patient via the breathing circuit. Each setting control is selectable to a level setting. Each ventilator setting control generates a ventilator setting parameter signal indicative of the current level setting of the ventilator setting control. The sensors measure ventilation support parameters. Each sensor is connected to a patient...

...an output signal based on the measured ventilation support parameter.

The processing subsystem has a **processor** and a **memory** . The **processor** runs under **control** of a program stored in the **memory** . It has an intelligence **system** that determines a desired level setting of at least one **ventilator** setting control in response to the **ventilator** setting parameter signal and the output signals. It generates a response signal based on the determination. The feedback **system** adjusts at least one of the level settings of the **ventilator** setting controls of the **ventilator** .

...An INDEPENDENT CLAIM is also included for a **method** of controlling pulmonary ventilation for a **ventilator** comprising...

...a) receiving at least one **ventilator** setting parameter signal indicative of the level setting of one **ventilator** setting control...

...c) controlling the level settings of the **ventilator** setting controls in response to the received **ventilator** setting parameter signal and the output signals...

...in fluid communication with at least one lung of a patient for treating patients with **respiratory** failure...

...breathing load expended by the patient (a) to avoid unnecessary medical complications of the required **respiratory** support; (b) to prevent further damage to a weakened patient; or (c) if it is beyond the capacity or capability of small or disabled patients. The **ventilator** delivers the most appropriate **mode** and intra- **mode** , the most appropriate quality and quantity of ventilation support required by the patient's current physiological needs by (i) receiving **ventilator** support signals indicative of the sufficiency of ventilation support received by the patient; (ii) receiving at least one **ventilator** signal indicative of the level settings of the **ventilator** setting controls of the **ventilator** ; and (iii) determining the desired level settings of the **ventilator** setting controls of the **ventilator** to provide the appropriate quality and quantity of ventilation support to the patient...

...The figure shows a block diagram of the **ventilator** monitor **system** .

... **Ventilator** (20

Technology Focus:

... i) arterial blood gas pH level of the patient. The ventilation setting control of the **ventilator** comprises (a) a minute ventilation (VE) control to set the VE level setting on the **ventilator** ; (b) a **ventilator** breathing frequency (f) control to set the (f) level setting on the **ventilator** ; (c) an intermittent mandatory ventilation rate ( IMV ) control to set the IMV level setting on the **ventilator** ; (d) a tidal volume (VT) control to set the VT level setting on the **ventilator** ; (e) a breathing gas flow rate (V) control to set the (V) level setting on the **ventilator** ; (f) a pressure limit control to set the pressure limit level setting on the **ventilator** ; (g) a work of breathing (WOB) control to set the WOB level setting on the **ventilator** ; (h) a pressure support ventilation (PSV) control to set the PSV level setting on the **ventilator** ; (i) a positive end expiratory pressure ( PEEP ) control to set the ( PEEP ) level setting on the **ventilator** ; (j) a continuous positive airway pressure ( CPAP ) control to set the CPAP level setting on the **ventilator** ; or (k) a fractional inhaled oxygen concentration (FIO2) control to set the FIO2 level setting on

the ventilator .

...

...Preferred Device : The ventilator further comprises (a) an oxygen control subsystem; (b) actuator(s); (c) display (62), where the processing subsystem (40) provides the desired level settings of the ventilator setting controls to the display; and (b) an alarm (21) for notifying an operator of the ventilator that the level settings of the ventilator setting has been adjusted...

...Preferred Component: The feedback system adjusts the level setting(s) of the ventilator setting controls to vary (a) a minute ventilation (VE) level; (b) a ventilator breathing frequency (f) level; (c) a tidal volume (VT) level; (d) a breathing gas flow...

...WOB) level; (g) a pressure support ventilation (PSV) level; (h) a positive end expiratory pressure ( PEEP ) level; (i) a continuous positive airway pressure ( CPAP ) level; or (j) a fractional inhaled oxygen concentration (FIO2) level, to maintain the sufficiency of...

...patient. It generates at least one driver signal responsive to the response signal. The feedback system comprises (a) a source of breathing gas(es); (b) a pneumatic subsystem in communication with...

...the breathing circuit; and (c) actuator(s) coupled to the pneumatic subsystem and to the ventilator setting control so that the breathing gas supplied to the patient is governed in response to the driver signal. The processing subsystem has neural network(s) and processor . The processor , in determining the desired level settings of the ventilator setting controls, generates ventilation data from the output signals of the sensors. It applies at least a portion of the ventilation data and at least a portion of the ventilator setting parameter signal to the neural network.

...Title Terms: PROCESS ;

International Patent Class (Main): A61M-016/00

International Patent Class (Additional): A62B-007/00

31/3,K/61 (Item 61 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

013684079 \*\*Image available\*\*  
WPI Acc No: 2001-168303/200117  
XRAM Acc No: C01-050170  
XRPX Acc No: N01-121405

Ventilation support monitoring system for a ventilator comprises input, sensors, and a processing subsystem that receives the output signals from the sensors and the ventilator setting parameter signal from the input

Patent Assignee: UNIV FLORIDA (UYFL ); UNIV FLORIDA RES FOUND INC (UYFL )  
Inventor: BANNER M J; BLANCH P B; EULIANO N R; PRINCIPE J C

Number of Countries: 023 Number of Patents: 004

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200100264	A1	20010104	WO 2000US18175	A	20000630	200117 B
AU 200060640	A	20010131	AU 200060640	A	20000630	200124
EP 1189649	A1	20020327	EP 2000946958	A	20000630	200229
			WO 2000US18175	A	20000630	
US 6796305	B1	20040928	US 99141735	P	19990630	200464
			US 2000608200	A	20000630	

Priority Applications (No Type Date): US 99141735 P 19990630; US 2000608200 A 20000630

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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WO 200100264	A1	E	54	A61M-016/00	
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Designated States (National): AU CA JP

Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

AU 200060640	A			A61M-016/00	Based on patent WO 200100264
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EP 1189649	A1	E		A61M-016/00	Based on patent WO 200100264
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Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

US 6796305	B1			A61M-016/00	Provisional application US 99141735
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Ventilation support monitoring system for a ventilator comprises input, sensors, and a processing subsystem that receives the output signals from the sensors and the ventilator setting parameter signal from the input

Abstract (Basic):

... A ventilation support monitoring **system** comprises an input that receives at least one **ventilator** setting parameter signal; sensors for measuring ventilation support parameters; and a processing subsystem connected to receive the output signals from the sensors and the **ventilator** setting parameter signal from the input.

... A ventilation support monitoring **system** comprises an input that receives at least one **ventilator** setting parameter signal; sensors (52) for measuring ventilation support parameters; and a processing subsystem connected to receive the output signals from the sensors and the **ventilator** setting parameter signal from the input. Each sensor connects to a select one of the...

...an output signal based on the measured ventilation support parameter.

The processing subsystem has a **processor** and a **memory**. The **processor** runs under **control** of a program stored in the **memory**. It has an intelligence **system** that determines a desired level setting of at least one **ventilator** setting control in response to the



**ventilator** setting parameter signal and the output signals...

...1) a ventilation support monitoring **method** for a **ventilator** (20) having selectable **ventilator** setting controls for governing supply of the breathing gas from the **ventilator** to the patient, each setting control selectable to a level setting comprising...

...a) receiving at least one **ventilator** setting parameter signal indicative of the level setting of one **ventilator** setting control...

...c) determining the desired level setting of at least one **ventilator** setting control of the **ventilator**. Each sensor is connected to a select one of the patient or the breathing circuit...

...2) a **method** for differential determination of desired level settings of a **ventilator** comprises...

...a) supplying a breathing gas from the **ventilator** to a patient via a breathing circuit in fluid communication with the **ventilator** and at least one lung of the patient...

...c) receiving **ventilator** setting parameter signals indicative of the level settings of the **ventilator** setting controls...

...at least a portion of the ventilation data and at least a portion of the **ventilator** setting parameter signals...

...f) converting the selected portion of the ventilation data and the selected portion of the **ventilator** setting parameter signals into numerical expressions...

...i) determining at least one of the desired level settings of the **ventilator** setting controls using the neural network in accordance with the input numerical expressions...

...For a **ventilator** supplying breathing gas to a patient via a breathing circuit in fluid communication with at least one lung of a patient for treating patients with **respiratory** failure...

...b) if it is beyond the capacity or capability of small or disabled patients. The **ventilator** monitor **system** delivers the most appropriate **mode** and intra- **mode**, the most appropriate quality and quantity of ventilation support required by the patient's current physiological needs by (a) receiving **ventilator** support signals indicative of the sufficiency of ventilation support received by the patient; (b) receiving at least one **ventilator** signal indicative of the level settings of the **ventilator** setting controls of the **ventilator**; and (c) determining the desired level settings of the **ventilator** setting controls of the **ventilator** to provide the appropriate quality and quantity of ventilation support to the patient  
...

...The figure shows a block diagram of the **ventilator** monitor **system**.

... **Ventilator** (20

Technology Focus:

... level of the patient; or (i) arterial blood gas pH level of the patient. The **ventilator** setting parameter signal and the desired level setting for the **ventilator** setting control of the **ventilator** comprise (a) a minute ventilation (VE) signal indicative of the VE

level set on the **ventilator** ; (b) a **ventilator** breathing frequency (f) signal indicative of the f level set on the **ventilator** ; (c) a tidal volume (VT) signal indicative of the VT level set on the **ventilator** ; (d) a breathing gas flow rate (V) signal indicative of the V level set on the **ventilator** ; (e) a pressure limit signal indicative of the pressure limit set on the **ventilator** ; (f) a work of breathing (WOB) signal indicative of the WOB level set on the **ventilator** ; (g) a pressure support ventilation (PSV) signal indicative of the PSV level set on the **ventilator** ; (h) a positive end expiratory pressure ( **PEEP** ) signal indicative of the **PEEP** level set on the **ventilator** ; (i) a continuous positive airway pressure ( **CPAP** ) signal indicative of the **CPAP** level set on the **ventilator** ; or (j) a fractional inhaled oxygen concentration (FIO2) signal indicative of the FIO2 level set on the **ventilator** . Preferred **System** : The **system** further comprises (a) a display (62), where the processing subsystem (40) provides the desired level settings of the **ventilator** setting controls to the display; and (b) an alarm (21) for notifying an operator of the **ventilator** that the level settings of the **ventilator** setting controls differs from the determined desired level settings of the **ventilator** setting controls...

...processing subsystem has (a) neural network(s) under control of a program stored in the **memory** , and (b) a mechanism for training the neural work. It is programmed with a set...

...rules, and identifies ventilation data used to (a) determine the desired level settings of the **ventilator** setting controls; (b) identifies a subset of the ventilation data for display; and (c) provides...

...ventilation data to the display. The processing subsystem provides the desired level settings of the **ventilator** controls to the display. The **processor** , in determining the desired level settings of the **ventilator** setting controls, generates ventilation data from the output signals of the sensors. It applies the...

...data prior to applying the portion of the ventilation data and the portion of the **ventilator** setting parameter signal to the neural network to generate the desired level settings of the **ventilator** setting controls.

...Title Terms: **SYSTEM** ;

International Patent Class (Main): A61M-016/00

31/3,K/76 (Item 76 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

012104071 \*\*Image available\*\*  
WPI Acc No: 1998-520983/199844  
XRPX Acc No: N98-406879

Graphic user interface for patient ventilator - has on-screen buttons allowing user to select proposed ventilator setting in any order and value, while processor controls ventilator using currently used parameters

Patent Assignee: NELLCOR PURITAN BENNETT INC (NELL-N); ARNETT D (ARNE-I); BUTTERBRODT J (BUTT-I); FERGUSON H L (FERG-I); SANBORN W G (SANB-I); WALLACE C L (WALL-I)

Inventor: ARNETT D; BUTTERBRODT J; FERGUSON H L; SANBORN W G; WALLACE C L

Number of Countries: 022 Number of Patents: 010

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9841270	A1	19980924	WO 98US3756	A	19980224	199844 B
AU 9863398	A	19981012	AU 9863398	A	19980224	199907
US 5915379	A	19990629	US 97818201	A	19970314	199932
EP 968019	A1	20000105	EP 98907643	A	19980224	200006
			WO 98US3756	A	19980224	
AU 735793	B	20010712	AU 9863398	A	19980224	200147
JP 2001521415	W	20011106	JP 98540524	A	19980224	200203
			WO 98US3756	A	19980224	
US 6369838	B1	20020409	US 97818201	A	19970314	200227
			US 99314860	A	19990519	
US 20020099477	A1	20020725	US 97818201	A	19970314	200254
			US 99314860	A	19990519	
			US 200299824	A	20020315	
EP 968019	B1	20030212	EP 98907643	A	19980224	200313
			WO 98US3756	A	19980224	
DE 69811346	E	20030320	DE 611346	A	19980224	200327
			EP 98907643	A	19980224	
			WO 98US3756	A	19980224	

Priority Applications (No Type Date): US 97818201 A 19970314; US 99314860 A 19990519; US 200299824 A 20020315

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
WO 9841270	A1 E	44	A61M-016/00	
			Designated States (National): AU CA JP	
			Designated States (Regional): AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE	
AU 9863398	A		A61M-016/00	Based on patent WO 9841270
US 5915379	A		A61M-016/00	
EP 968019	A1 E		A61M-016/00	Based on patent WO 9841270
			Designated States (Regional): AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE	
AU 735793	B		A61M-016/00	Previous Publ. patent AU 9863398
				Based on patent WO 9841270
JP 2001521415	W	81	A61M-016/00	Based on patent WO 9841270
US 6369838	B1		A61M-016/00	Cont of application US 97818201
US 20020099477	A1		G05D-023/00	Cont of application US 97818201
				Cont of application US 99314860
				Cont of patent US 5915379
				Cont of patent US 6369838
EP 968019	B1 E		A61M-016/00	Based on patent WO 9841270
			Designated States (Regional): AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE	

DE 69811346 E

A61M-016/00

Based on patent EP 968019

Based on patent WO 9841270

Graphic user interface for patient ventilator - ...

...has on-screen buttons allowing user to select proposed ventilator setting in any order and value, while processor controls ventilator using currently used parameters

...Abstract (Basic): The interface comprises programmable processor (30) responsive to selected ventilation parameters for controlling respirator to ventilate patient, and a memory (35) connected to the processor for storing ventilation parameters. The interface also includes user inputs (25) and a display (50) for displaying ventilation parameters, including those used by the processor to control the respirator and proposed ventilation parameters. The user inputs cooperate with the memory and the display for selecting one of the proposed ventilation parameters and for assigning values...

...The proposed ventilator parameters may be selected in any order and values assigned to the proposed parameters while the processor controls ventilator using currently used values of the ventilation parameters. A user accepts one or more assigned values of the proposed ventilator parameters by pressing a button and the processor stores the assigned proposed ventilator values in the memory, and controls the ventilator using the newly stored values. Preferably, the display further includes a graphical representation of a...

...Title Terms: PROCESSOR ;

International Patent Class (Main): A61M-016/00 ...

International Patent Class (Additional): A61B-005/08

31/3,K/93 (Item 93 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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009748249 \*\*Image available\*\*  
WPI Acc No: 1994-028100/199404  
XRPX Acc No: N94-021801

Respiratory equipment including nebuliser for atomised spray - has  
computerised monitoring system recording applied doses of gas on  
magnetic tape or memory chip

Patent Assignee: TAEMA (TAEM-N); AIR LIQUIDE SANTE INT (AIRL )

Inventor: DESFORGES D; WILLEMOT J

Number of Countries: 015 Number of Patents: 009

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 580517	A1	19940126	EP 93401912	A	19930723	199404 B
FR 2693910	A1	19940128	FR 929075	A	19920723	199408
BR 9302959	A	19940222	BR 932959	A	19930722	199411
CA 2101044	A	19940124	CA 2101044	A	19930721	199415
ZA 9305317	A	19940427	ZA 935317	A	19930722	199422
US 5560353	A	19961001	US 9395709	A	19930723	199645
			US 94350018	A	19941129	
EP 580517	B1	20010321	EP 93401912	A	19930723	200117
DE 69330041	E	20010426	DE 630041	A	19930723	200130
			EP 93401912	A	19930723	
ES 2156123	T3	20010616	EP 93401912	A	19930723	200141

Priority Applications (No Type Date): FR 929075 A 19920723

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

EP 580517 A1 F 5 A61M-016/10

Designated States (Regional): BE DE DK ES GR IT LU NL PT SE

FR 2693910 A1 10 A61M-016/10

BR 9302959 A A61M-016/00

CA 2101044 A F A61M-011/00

ZA 9305317 A 12 A61M-000/00

US 5560353 A 5 A61M-016/00 Cont of application US 9395709

EP 580517 B1 F A61M-016/10

Designated States (Regional): BE DE DK ES GR IT LU NL PT SE

DE 69330041 E A61M-016/10 Based on patent EP 580517

ES 2156123 T3 A61M-016/10 Based on patent EP 580517

Respiratory equipment including nebuliser for atomised spray...

...has computerised monitoring system recording applied doses of gas on  
magnetic tape or memory chip

...Abstract (Basic): The respiratory equipment includes a nebuliser (1)  
in a circuit (2) between a source of gas (3) and the patient's  
respiratory channels. A three channel valve (5) is fitted in the dose  
of carrier gas, and...

...recorded, either on a multi-track magnetic tape or on a non-volatile or  
'flash' memory chip. This information includes the number and  
duration of the pulses applied when operating in one of several modes

...Abstract (Equivalent): A system for supplying to a respiratory tract  
of a user a plurality of discrete puffs of at least one gas, each of  
the puffs containing particles of at least one active product; the  
system comprising...

...a transportable **memory** storage unit for transporting the puff sequence program...

...means for the sequence-control programmable means to accept the puff sequence program from the **memory** storage unit and for recording timing parameters of the sequence of the puffs on the **memory** storage unit; and a programing station for entering the puff sequence program onto the **memory** storage unit...

...Title Terms: **COMPUTER** ;

International Patent Class (Main): **A61M-000/00** ...

... **A61M-011/00** ...

... **A61M-016/00** ...

... **A61M-016/10**

31/3,K/100 (Item 100 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

009014807 \*\*Image available\*\*  
WPI Acc No: 1992-142143/199218  
XRPX Acc No: N92-106338

**Mobile respirator monitor with pressure gauge - has transmitter with control for spacing of transmission signals, and identification signal generator**

Patent Assignee: UWATEC AG (UWAT-N); HOISL I (HOIS-I)  
Inventor: MOCK M; VOLLM E; VOELLM E; MUECK M; VOELLM E B  
Number of Countries: 016 Number of Patents: 010  
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
DE 4033292	A	19920423	DE 4033292	A	19901019	199218	B
WO 9206889	A1	19920430	WO 91EP1982	A	19911018	199220	
EP 550649	A1	19930714	EP 91918293	A	19911018	199328	
			WO 91EP1982	A	19911018		
EP 550649	B1	19940504	EP 91918293	A	19911018	199418	
			WO 91EP1982	A	19911018		
DE 59101589	G	19940609	DE 501589	A	19911018	199424	
			EP 91918293	A	19911018		
			WO 91EP1982	A	19911018		
JP 6504245	W	19940519	JP 91516867	A	19911018	199424	
			WO 91EP1982	A	19911018		
ES 2056662	T3	19941001	EP 91918293	A	19911018	199440	
US 5392771	A	19950228	WO 91EP1982	A	19911018	199514	
			US 92861832	A	19920817		
US 5738092	A	19980414	US 92861832	A	19920817	199822	
			US 94311150	A	19940923		
			US 96720215	A	19960926		
EP 550649	B2	20000301	EP 91918293	A	19911018	200016	
			WO 91EP1982	A	19911018		

Priority Applications (No Type Date): DE 4033292 A 19901019

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
DE 4033292	A		19		
EP 550649	B2	G		B63C-011/32	Based on patent WO 9206889
				Designated States (Regional):	AT CH DE ES FR GB IT LI
WO 9206889	A1	G	53	B63C-011/32	
				Designated States (National):	JP US
				Designated States (Regional):	AT BE CH DE DK ES FR GB GR IT LU NL SE
EP 550649	A1	G		B63C-011/32	Based on patent WO 9206889
				Designated States (Regional):	AT CH DE ES FR GB IT LI
EP 550649	B1	G	28	B63C-011/32	Based on patent WO 9206889
				Designated States (Regional):	AT CH DE ES FR GB IT LI
DE 59101589	G			B63C-011/32	Based on patent EP 550649
					Based on patent WO 9206889
JP 6504245	W			B63C-011/32	Based on patent WO 9206889
ES 2056662	T3			B63C-011/32	Based on patent EP 550649
US 5392771	A		18	A62B-007/00	Based on patent WO 9206889
US 5738092	A		18	A62B-007/00	Div ex application US 92861832
					Cont of application US 94311150
					Div ex patent US 5392771

**Mobile respirator monitor with pressure gauge...**

...Abstract (Basic): The mobile **respirator** monitor contains a pressure sensor for the **respirator** pressure containers, a transmitter of

signals corresp. to the pressure measuring at intervals, a receiver...

...interval and compared in the receiver with a stored identification signal. Received signals are only **processed** on the signal coincidence ...

...Abstract (Equivalent): The mobile **respirator** monitor contains a pressure sensor for the **respirator** pressure containers, a transmitter of signals corresp. to the pressure measuring at intervals, a receiver ...

...interval and compared in the receiver with a stored identification signal. Received signals are only **processed** on the signal coincidence ...

...EP-550649 A monitoring **device** for a portable **breathing apparatus** having: a pressure measuring means, which detects the pressure in one or more pressure containers of the **breathing apparatus** by means of a pressure sensor and emits an electrical pressure signal, which is representative...

...to this receiving means, which receives the transmission signal, emitted by the transmission means; a **microprocessor** means, arranged in the receiver means, which is controlled by a program, stored in a **memory** arranged in this receiving means, said **microprocessor** means calculating the pressure value, measured by the pressure measuring means from the received transmission...

...which is assigned to that of an associated individual transmitter means is stored in the **memory** of the receiver means, that the receiver means comprises a comparison means, which uses this...

...Abstract (Equivalent): The **respirator** monitor **device** has a manometer for sensing the pressure in the pressure container of the **breathing apparatus** and has a transmitter so that a signal corresponding to the pressure is transmitted at...

...received and tested by a receiver. If the identification signal matches an identification comparison signal **stored** in the receiving **device**, the measured pressure value is displayed on a display device...

International Patent Class (Main): **A62B-007/00** ...

International Patent Class (Additional): **A62B-007/04** ...

... **A62B-009/00** ...

... **A62B-027/00**



31/3,K/104 (Item 104 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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007472113

WPI Acc No: 1988-106047/198816

XRFX Acc No: N88-080439

processor - controlled monitoring of respiration.- storing component  
models of appts. and patient and recalling to form complete model

Patent Assignee: INGENIEUR DRESDEN (INGE-N)

Inventor: BOEHME B; KAISER S; MORGENSTE U; WOSCHECH S

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
DD 251706	A	19871125	DD 293085	A	19860730	198816 B

Priority Applications (No Type Date): DD 293085 A 19860730

processor - controlled monitoring of respiration...

...storing component models of appts. and patient and recalling to form  
complete model

...Abstract (Basic): are formed from the appts. parameters and the  
parameters of its elements. A patient component model is defined from  
identification characteristics. Both component models are stored in the  
computer section of the artificial respiration system. These are  
then called up from the memory and combined to form a complete model

...

...If there are any changes of parameters during respiration the necessary  
ventilator setting may be determined, without harm to the patient, by  
simulation...

...USE/ADVANTAGE - Enables doctor to respond by ventilator adjustment to  
changes of parameters of appts. or of the patient, without causing any  
additional

Title Terms: PROCESSOR ;

International Patent Class (Additional): A61M-016/00

31/3,K/105 (Item 105 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

007254956

WPI Acc No: 1987-251963/198736

XRPX Acc No: N87-188535

Programmable fluid flow controller for respiratory system - uses  
transducers to sense parameters for input to control unit which opens or  
closes distribution circuits

Patent Assignee: SOC FAB INSTR MESUR (INST-N)

Inventor: SILBER G; VINCENT D

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
FR 2593299	A	19870724	FR 86696	A	19860120	198736 B

Priority Applications (No Type Date): FR 86696 A 19860120

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
FR 2593299	A	28		

Programmable fluid flow controller for respiratory system -

...Abstract (Basic): A number of fluid flow distribution circuits (2)  
connected to **respirators** are supplied through a tube (PA) to a  
pressurised source of air and gas. An electronic control unit (3)  
contains A/D and D/A converters connected to a **microprocessor** and its  
**memory** and controls the opening or closing of each distribution  
circuit. The control actions follow a...

...Title Terms: **SYSTEM** ;

International Patent Class (Additional): **A61M-016/06** ...

... **A62B-007/14**

31/3,K/107 (Item 107 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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007042512

WPI Acc No: 1987-042509/198706

XRFX Acc No: N87-032359

**Pulmonary ventilator controller for anaesthetised patient - has  
microprocessor receiving from operator target values for minute volume  
breathing rate and expiration-inspiration time ratio**

Patent Assignee: RUSZ T (RUSZ-I)

Inventor: RUSZ T

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 4637385	A	19870120	US 86818005	A	19860113	198706 B

Priority Applications (No Type Date): US 86818005 A 19860113

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
US 4637385	A	6		

**Pulmonary ventilator controller for anaesthetised patient...**

...has microprocessor receiving from operator target values for minute volume breathing rate and expiration-inspiration time ratio

...Abstract (Basic): The pulmonary ventilator system has a bellows assembly and a source of driving gas connected by a series branch...

...controlled switching valve and a motor-controlled flow-rate-controlling valve. A controller including a microprocessor senses the position of the flow-rate-controlling valve via a mechanical to electrical transducer...

...has outputs connected to and controlling the switching valve and the motor. Programmed in the memory are the maximum flow rate capacity of the flow-rate-controlling valve and the maximum capacity of the bellows. The microprocessor is capable of receiving from an operator his target values for minute volume, breathing rate...

...the flow-controlling valve and or greater than the bellows can handle, it reinstructs the ventilator system to employ a new and realizable value of breathing rate and/or expiration time to...

...Title Terms: MICROPROCESSOR ;

International Patent Class (Additional): A61M-016/00

31/3,K/113 (Item 113 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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003277595

WPI Acc No: 1982-C5580E/198210

Patient respiration monitoring appts. - uses transducer sensing of  
air-way pressure and volume flow for input to computerised processing and  
monitoring circuit

Patent Assignee: TOKYO SHIBAURA ELECTRIC CO (TOKE )

Inventor: ITOH A

Number of Countries: 005 Number of Patents: 004

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 46570	A	19820303	EP 81106455	A	19810819	198210 B
US 4444201	A	19840424	US 81294290	A	19810819	198419
EP 46570	B	19850717				198529
DE 3171395	G	19850822				198535

Priority Applications (No Type Date): JP 80118162 A 19800827

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
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EP 46570	A	E 25		
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Designated States (Regional): DE FR GB NL

EP 46570	B	E		
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Designated States (Regional): DE FR GB NL

...Abstract (Basic): One end of the transducer (14) is connected to a tube (12) intubated into the **respiratory** tract of the patient, whilst the other end is connected to an artificial **respiration device** (18) through a bellows type tube (16). The transducer enables measurement to be taken of the amount of air breathed by the patient and the airway pressure in his **respiratory** tract. A pressure in the transducer is conducted to the manometer (22) which is in...

...via an analog-to- digital converter (30)in the processing circuit which also includes a **CPU** , and bubble **memory** in addition to video **RAM** , ROM and **RAM** memories. The device has an additional keyboard (46) for data entry and output monitoring (44...

...Title Terms: **COMPUTER** ;

International Patent Class (Additional): **A61B-005/08** ...

... **A61M-016/00**

31/3,K/114 (Item 114 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
(c) 2004 Thomson Derwent. All rts. reserv.

003120224

WPI Acc No: 1981-N0277D/198151

Patients respiratory parameter determin. appts. - uses time controlled  
integrator connected to flow sensor and periodically cleared memory  
and calculator to obtain pneumatic parameters

Patent Assignee: DRAEGERWERK AG (DRAG )

Inventor: BAEUERLE R; HORNAUER D

Number of Countries: 005 Number of Patents: 007

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
GB 2077444	A	19811216	GB 8117329	A	19810605	198151 B
DE 3021326	A	19811217				198152
FR 2483769	A	19811211				198203
SE 8102322	A	19820104				198203
NL 8101088	A	19820104				198205
GB 2077444	B	19840222				198408
SE 453884	B	19880314				198813

Priority Applications (No Type Date): DE 3021326 A 19800606

Patent Details:

Patent No	Kind	Lan Pg	Main IPC	Filing Notes
GB 2077444	A	6		

Patients respiratory parameter determin. appts...

...uses time controlled integrator connected to flow sensor and  
periodically cleared memory and calculator to obtain pneumatic  
parameters

...Abstract (Basic): connected to a calculating unit (6), and optionally to  
a storage unit (8). During each **respiratory** cycle the monitoring unit  
(7) supplies the calculating unit (6) with at least two sets...

...the volume from which the calculating unit (6) then calculates the  
required parameters of the **respiratory** system...

...pressure. Pref. the calculations are performed using a Least squares  
technique. The stored values are **cleared** at the end of each  
**operating** cycle...

...Title Terms: **MEMORY** ;

International Patent Class (Additional): **A61B-005/08** ...

... **A61M-016/00**

*See  
claim  
2  
of  
"GB  
version"*

31/3,K/117 (Item 117 from file: 350)  
DIALOG(R)File 350:Derwent WPIX  
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003021296

WPI Acc No: 1981-C1309D/198110

Pulmonary analyser to compute respiratory characteristics - having  
spirometer for exhaled breath, VCO, digital computer , RAM , ROM and  
nine-digit display

Patent Assignee: JONES MED INSTRU (JONE-N)

Inventor: HARWOOD C; JONES W C

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 4250890	A	19810217				198110 B

Priority Applications (No Type Date): US 7914423 A 19790223

Pulmonary analyser to compute respiratory characteristics...

...having spirometer for exhaled breath, VCO, digital computer , RAM ,  
ROM and nine-digit display

...Abstract (Basic): The self-contained, portable system is for measuring  
and computing respiratory parameters of a test subject undergoing  
forced expired breathing manoeuvres according to instructions including  
a...

...receiving the exhaled breath of the subject for generating a measurement  
signal, a miniaturised digital computer for receiving the measurement  
signal and a visual display for presenting alpha-numeric characters  
under control of the computer to generate indicia representative of  
the computed parameter results...

...The computer further includes a central processing unit and a  
voltage control oscillator interconnected between the central  
processing unit and the spirometer for receiving the measurement  
signal from the spirometer and converting the same to digital signals  
for averaging by the central processing unit to eliminate random  
noise.

...Title Terms: COMPUTER ;

International Patent Class (Additional): A61B-005/08

31/3,K/126 (Item 126 from file: 347)  
DIALOG(R)File 347:JAPIO  
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06590221 \*\*Image available\*\*  
VENTILATION DATA PROCESSING METHOD AND DEVICE

PUB. NO.: 2000-176016 [JP 2000176016 A]  
PUBLISHED: June 27, 2000 (20000627)  
INVENTOR(s): UTSUNOMIYA HIDETAKA  
YOKOO TADASHI  
APPLICANT(s): NIPPON KODEN CORP  
APPL. NO.: 10-354750 [JP 98354750]  
FILED: December 14, 1998 (19981214)

VENTILATION DATA PROCESSING METHOD AND DEVICE

INTL CLASS: A61M-016/00

#### ABSTRACT

...the mouth of a patient, and the outputs of these sensors are inputted to a ventilation data processing device. After starting the operation of the ventilation data processing device, the outputs of both the sensors are read to recognize one respiration from expiration flow data. In the one recognized respiration, expiration end and positive expiration end pressure-( PEEP ) are determined, and the respective values are stored in a memory 8. After PEEP is changed, it is judged whether the respiration is performed n2 times or more, and in the case of YES, the respective changes are determined from the expiration end and PEEP in the memory 8. The compliance is calculated by use of both the changes, and the result is stored in the memory 8 and also displayed on a display means 9.

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Set	Items	Description
S1	9643	(VENTILAT? OR RESPIRAT? OR BREATH?) (3N) (DEVICE? OR UTENSIL? OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN- C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2	44905	VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR HFV OR IMV OR IPAP OR CPAP OR PEEP OR CPAP
S3	1022466	CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE- T? OR OVERRID? OR OVERWRT? OR OVER() (RIDE? OR RIDING OR WRIT- ?) OR REPROGRAM? OR REMOV?
S4	1279284	OPERAT? OR FUNCTION?
S5	560068	PERFORMANC? OR WORKING? OR EXECUTI?
S6	674783	DATA? OR PROGRAM?
S7	372635	RUN OR RUNS OR RUNNING OR RAN
S8	104684	(READ? OR SCAN? OR DECOD?) (5N) (WRIT? OR CODE? OR CODING? OR CODIF?)
S9	16743	(CHIP? OR SMART? OR DEBIT? OR PROGRAMABL? OR PROGRAMMABL?) - (3N) CARD? OR SMARTCARD? OR CHIPCARD?
S10	145797	(STORE? OR STORING? OR STORAGE) (3N) (DEVICE? OR MEDIUM? OR - ELECTRONIC? OR OPTIC? OR MAGNET?) OR USER?() INTERFACE?
S11	318129	CACHE? OR MEMORY? OR RAM OR (EXTERNAL OR REMOVABL? OR DETA- CHABL? OR STANDALONE OR STAND() ALONE OR PORTABL OR INSERTABL? - ) (2N) (UNIT? OR DEVICE?)
S12	246300	CPU OR CPUS OR PROGRAM?() CONTROL? OR PROCESS? (2N) CONTROL? - OR MICROPROCESS? OR DATAPROCESS? OR CENTRALPROCESS? OR (MICRO OR DATA OR CENTRAL) () PROCESS?
S13	143057	PROCESS?() UNIT? OR WORKSTATION? OR WORK() STATION? OR DESK- OP? OR DESK() (TOP OR TOPS) OR SERVER?
S14	363805	COMPUTER OR COMPUTERS OR PC OR PCS
S15	1376491	METHOD? ?
S16	1199862	SYSTEM? ?
S17	1064521	PROCESS??
S18	470421	PROCEDUR?
S19	605450	TECHNIQU?
S20	645646	MODE? ?
S21	103710	IC=(A62B? OR A61M? OR F16K? OR A61B?)
S22	6584	S1:S2 AND S21
S23	49516	S22 OR S1:S2
S24	12315	S23 AND S9:S11
S25	17190	S23 AND S12:S14
S26	7193	S24 AND S25
S27	1990	S26 AND S3(5N)S4:S11
S28	102	S27 AND S1:S2(5N)S9:S14
S29	1202	S27 AND S15:S20(5N)S3
S30	136	S29 AND S21
S31	211	S28 OR S30
S32	211	IDPAT (sorted in duplicate/non-duplicate order)

? show files

File 348:EUROPEAN PATENTS 1978-2004/Oct W01

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File 349:PCT FULLTEXT 1979-2002/UB=20041007,UT=20040930

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32/3,K/2 (Item 2 from file: 348)  
DIALOG(R)File 348:EUROPEAN PATENTS  
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00744748

SYSTEM FOR OPTIMIZING CONTINUOUS POSITIVE AIRWAY PRESSURE FOR TREATMENT OF  
OBSTRUCTIVE SLEEP APNEA

SYSTEM FUR DIE OPTIMIERUNG DES KONTINUIERLICHEN, POSITIVEN ATEMWEGDRUCKS  
ZUR BEHANDLUNG DES ATEMSTILLSTANDES IM SCHLAF BEI VERLEGTE ATEMWEGEN  
SYSTEME PERMETTANT D'OPTIMISER LA PRESSION POSITIVE CONTINUE DES VOIES  
RESPIRATOIRES POUR LE TRAITEMENT DE L'APNEE OBSTRUCTIVE DU SOMMEIL

PATENT ASSIGNEE:

PURITAN-BENNETT CORPORATION, (1144916), 9728 Pflumm Road, P.O. Box 15915,  
Lenexa, KS 66285-5915, (US), (Proprietor designated states: all)  
NEW YORK UNIVERSITY, (300274), 550 First Avenue, New York, NY 10016, (US)  
, (Proprietor designated states: all)

INVENTOR:

RAPOPORT, David, M., 214 West 17th Street 4A, New York, NY 10011, (US)  
NORMAN, Robert, G., 306 Shore Drive, New Windsor, NY 12553, (US)

LEGAL REPRESENTATIVE:

Belcher, Simon James (58311), Urquhart-Dykes & Lord Tower House Merrion  
Way, Leeds LS2 8PA, (GB)

PATENT (CC, No, Kind, Date): EP 759791 A1 970305 (Basic) = (US) 5490502  
EP 759791 B1 020814  
WO 9532016 951130

APPLICATION (CC, No, Date): EP 95920447 950516; WO 95US6069 950516

PRIORITY (CC, No, Date): US 246964 940520

DESIGNATED STATES: BE; CH; DE; ES; FR; GB; LI; SE

RELATED DIVISIONAL NUMBER(S) - PN (AN):

EP 1172123 (EP 2001126195)

INTERNATIONAL PATENT CLASS: A61M-016/00 ; A61B-005/00 ; G06F-017/00

NOTE:

No A-document published by EPO

LANGUAGE (Publication,Procedural,Application): English; English; English

FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS B	(English)	200233	543
CLAIMS B	(German)	200233	465
CLAIMS B	(French)	200233	637
SPEC B	(English)	200233	8972
Total word count - document A			0
Total word count - document B			10617
Total word count - documents A + B			10617

INTERNATIONAL PATENT CLASS: A61M-016/00 ...

... A61B-005/00

...SPECIFICATION an optimum value in the treatment of obstructive sleep  
apnea, and more particularly to a **breathing device** which maintains  
constant positive airway pressure and method of use which analyzes an  
inspiratory flow...

...obstruction of the upper airway occurring during sleep. The obstruction  
results in a spectrum of **respiratory** disturbances ranging from the  
total absence of airflow (apnea) to significant obstruction with or  
without reduced airflow (hypopnea and snoring), despite continued  
**respiratory** efforts. The morbidity of the syndrome arises from  
hypoxemia, hypercapnia, bradycardia and sleep disruption associated...

...onset of sleep and may be exaggerated in OSAS.

Since 1981, continuous positive airway pressure ( CPAP ) applied by a tight fitting nasal mask worn during sleep has evolved as the most...

...535-542, discusses various polysomnographic techniques.

Despite its success, limitations to the use of nasal CPAP exist. These mostly take the form of discomfort from the mask and the nasal pressure...

...4655213 and US-5065756, as well as in "Therapeutic Options For Obstructive Sleep Apnea", Garay, Respiratory Management, Jul/Aug 1987, pp. 11-15; and "Techniques For Administering Nasal CPAP ", Rapaport, Respiratory Management, Jul/Aug 1987, pp. 18-21. Minimizing the necessary pressure remains a goal of...

...Because of this, most sleep laboratories currently prescribe the setting for home use of nasal CPAP pressure based upon the single highest value of pressures needed to obliterate apneas during a...

...in the patient's airway does not occur. In particular, the invention relates to a breathing device for adjusting a controlled positive pressure to the airway of a patient by detecting flow...limitation has been detected and on the previous actions taken by the system.

The preferred breathing device or apparatus consists of a flow generator, such as a variable-speed blower, a flow sensor, an analog to digital converter, a microprocessor , and a pressure controller, such as a blower motor speed control circuit, a patient connection...

...air through the flow sensor to the patient via a hose and nasal coupling. The microprocessor obtains the flow waveform from the digitized output of the flow sensor. Using the method of the present invention described herein, the microprocessor adjusts the speed of the blower via the motor control circuit to change the air...

...may be provided to measure the actual pressure in the patient hose. In addition, the microprocessor may store measured pressure and flow waveform values in its data memory to provide a history for real-time or off-line processing and analysis.

Other features...

...waveform of the airflow of a 30 second epoch to a sleeping patient from a CPAP generator, with a CPAP pressure of 10 cm H<sub>2</sub>O.

FIG. 2 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 8 cm H<sub>2</sub>O.

FIG. 3 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 6 cm H<sub>2</sub>O.

FIG. 4 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 4 cm H<sub>2</sub>O.

FIG. 5 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 2 cm H<sub>2</sub>O.

FIG. 6 is a simplified cross sectional view of...

...with the invention.

FIG. 10 is a flow diagram illustrating one technique for adjusting the CPAP pressure, in accordance with the invention.

FIG. 11 is a transition diagram of a three...

...plot of a total flow signal and a derivative of an inspiratory waveform depicting a **respiratory** effort index.

FIG. 16 contains a table of the probability factors used to modify the ...DETAILED DISCLOSURE OF THE INVENTION

FIGS. 1-5 illustrate the waveforms of flow from a **CPAP** generator, obtained during the testing of a patient, in sleep studies. In these tests, the patient was wearing a **CPAP** mask connected to an air source, in the manner illustrated in US-5 065 756...

...the source of air.

FIG. 1 illustrates a "normal" waveform, in this instance with a **CPAP** pressure of 10 cm H<sub>2</sub>O. This pressure was identified as corresponding to apnea free...

...airway occurs, prior to the occurrence of frank apnea, periodic breathing or arousal.

When the **CPAP** pressure was decreased to 8 cm H<sub>2</sub>O, as illustrated in FIG. 2, a partial...

...FIG. 4, when the controlled positive pressure was reduced to 4 cm. Reductions in the **CPAP** pressure from the pressure of apnea free respiration resulted in snoring by the patient. When...

...to the collapsible tube 12. With reference to FIG. 7, in this experiment, a commercial **CPAP** flow generator 14 is coupled to the "distal" end of the Starling resistor 10, and...

...the column 13 set between 5 and 15 cm H<sub>2</sub>O. The airflow from the **CPAP** flow generator was started at a pressure of 14 cm H<sub>2</sub>O, then sequentially decreased...

...e., at the port of the sinusoidal generator 15, and the lower curve illustrates the **CPAP** pressure. The gradations at the top of FIG. 8 denote seconds. FIG. 8 thus reflects...

...FIGS. 1-5, are employed in order to control the flow of air from a **CPAP** generator, to thereby minimize the flow of air from the generator while still ensuring that...

...does not occur.

In one embodiment of the invention, as illustrated in FIG. 9, a **CPAP** mask 20 is connected via tube 21 to receive air from a **CPAP** flow generator 22. These elements may be of the type disclosed in US-5 065 756, although the invention is not limited thereto, and any conventional **CPAP** system may alternatively be employed. A conventional flow sensor 23 is coupled to the tube...

...is of course apparent that, depending upon the type of flow generator 22, the signal **processor** may directly **control** the flow generator, instead of controlling a flow control device 25.

One method for adjusting the **CPAP** pressure in accordance with the invention is illustrated in FIG. 10. After the **CPAP** mask has been fitted to a patient and the **CPAP** generator has been connected to the mask (step 40), the **CPAP** pressure is set at a starting pressure. This pressure is a pressure at which flow...

...42).

If it is determined that flow limitation has occurred (step 43) and that the **CPAP** pressure is less than the maximum allowed (step 44), then the **CPAP** pressure is increased by 0.5 cm H<sub>2</sub>O...at the pressure comparing step 44 the pressure was not less than the maximum allowed

CPAP pressure, then the method returns to the settling step 41 without increasing the CPAP pressure.

If it was determined that a flow limitation was not present (step 43), then...

...made (step 46) whether a predetermined time has elapsed following the last change in the CPAP pressure. The predetermined time may be, for example, two minutes. If the predetermined time has...

...period step 41. If the predetermined minimum time has elapsed, it is determined whether the CPAP pressure is greater than the minimum allowed pressure (step 47). If it is greater than the minimum allowed pressure, then the CPAP pressure is decreased by 0.5 cm H<sub>2</sub>O (step 48), and the method returns...

...the settling step 41. Otherwise, the returns to the settling step 41 without decreasing the CPAP pressure.

While the above described example of the method of the invention employed CPAP pressure change steps of 0.5 cm H<sub>2</sub>O, it is apparent that the invention...

...pressure, or "start value," must be available for use when power-on occurs in the **breathing device**. Similarly, the method requires a "therapeutic level" of controlled positive pressure to return to whenever...

...of a valid breath. A valid breath is determined by a cyclical fluctuation in the **respiratory** signal superimposed on the constant system leak. This detection is implemented using a three phase...

...art, the logic for the state machine may be programmed into the software of a **microprocessor** or similar **computer** hardware.

The total flow signal present within the positive pressure flow generator is used as...to differentiate between the onset of inspiration and mere changes in flow leakage in the **breathing device**.

The average leak value (ALV) is a calculated running average of the actual flow signal...

...Also, the method steps may be applied to the estimated flow signal output of a CPAP generator (which has the constant leak value subtracted out) and the ALV set equal to...

...present is based on four shape detection parameters, the sinusoidal index, the flatness index, the **respiratory** effort index and the relative flow magnitude index. The sinusoidal parameter or index is calculated...

...parameter or index which ranges from 1 (sinusoidal) to 0 (flat).

The system calculates the **respiratory** effort index as the ratio of peak derivative (rate of change of flow with respect...

...derivative of the inspiratory flow. The ratio of the peak values (B/A) is the "**respiratory** effort index." This parameter is useful to detect flow limitation in a patient, because an increased **respiratory** effort is manifested in an increased slope of the inspiratory flow waveform.

The system calculates...allowing calculation of a posterior probability.

The four shape detection parameters (sinusoidal index, flatness index, **respiratory** effort index and relative flow magnitude index) are used in a mathematical function to determine...

...the patient. The steps of the method may be programmed in the software of a **microprocessor** or similar **computer**. As part of the decision process, the system calculates a time weighted majority function (MF... low limit or above the high limit reference values.

FIG 18. shows an alternative therapeutic **apparatus**. The **breathing device** 70 is composed of a flow sensor circuit 72 which senses the flow rate of...

...output value which is proportional to the analog voltage output from the flow sensor.

A **microprocessor** 80 with associated **memory** 81 and other peripheral circuits executes **computer** programs which implement the optimizing methods heretofore described. The **microprocessor** or similar computing device uses the digital output values from a multiplexer 76 and an analog-to-digital converter 78. The **microprocessor** produces a speed control signal which adjusts a motor speed control circuit 82 which controls...

...72. The speed of the blower determines the pressure in the patient circuit. Thus, the **microprocessor** is able to adjust the pressure of the patient circuit 70 in response to the data values from the flow sensor.

The **breathing device** 70 may also incorporate a pressure sensor circuit 90 to allow the **microprocessor** 80 to obtain a direct measurement of the pressure in the patient tubing 74 via the analog to digital converter circuit 78. Such a configuration would allow the **microprocessor** to maintain the pressure within the maximum and minimum pressure limits established by the prescribing physician. The actual operating pressure levels can be stored in the **memory** 81 of the **microprocessor** every few minutes, thus providing a history of pressure levels during the hours of use when the stored data values are read and further processed by a separate **computer** program.

A signal representative of the speed of the blower could be stored in **memory** instead of the pressure data values; however, such speed values do not change as rapidly...

...the home. Detection and measurement of inspiratory and expiratory flow can be from a standard **CPAP** system with a flow signal output or by a diagnostic system 100 as shown in...

...Data values representative of the measured inspiratory and expiratory flow can be logged by a **microprocessor** 110 in various forms of **computer memory** 114.

As shown in FIGS. 20 and 21, the detection and measurement of breathing gas...values may be continuously measured and recorded on a data logging device such as a **microprocessor** 110 having program **memory** 111 and a **storage medium** 114. Thus, the recorded flow signal may be analyzed during or after collection to categorize...

...airway resistance (not resulting in frank apnea) or to adjust a single prescription pressure of **CPAP** in a well standardized manner either in the laboratory or on the basis of home...

...FIG. 18, the flow waveforms may be recorded in a recording device, such as a **microprocessor** 80 with associated **memory** 81. As heretofore described, data values may be recorded while the patient is using a...

...is connected to a pressure or flow sensor 104 which supplies data values to a **microprocessor** 100 via a multiplexer 166 and analog-to-digital converter 118. Software for storing and analyzing the data may be stored in read-only program **memory** 111, while the data values are stored in random-access **memory** or non-volatile **memory** 114. Additionally, an

oximeter 120 and/or similar diagnostic devices may be connected to the patient and multiplexer for generating additional data values for use and storage by the **microprocessor** .

An alternative nasal connection could be achieved by using a "standard" nasal cannula commonly used...

...representative of the actual flow waveform shape.

The recording device may be configured with a **microprocessor** 110 which uses a sample-and-hold circuit, and an analog-to-digital converter 118...

...waveforms. The digitized samples are then stored in time-sequential order in a non-volatile **memory** device 114, e.g. magnetic disk drive, "flash" **memory** , or battery-backed random-access **memory** .

In order to record more than one signal, e.g. flow and pressure waveforms and...patient is using the diagnostic device at home, the digitized waveforms are stored in nonvolatile **memory** such as flash **memory** , floppy or hard disk, or battery-powered random-access **memory** ( **RAM** ). One or two additional measurements may optionally be recorded: patient sleeping position from a position...

...value per second for each additional measurement versus fifty values per second for flow), the **memory** storage requirements would not be increased significantly.

After using the diagnostic device to record the desired parameters while sleeping for one or more nights, the patient returns the **device** or data **storage** unit, e.g., a disk or non-volatile **memory** card, to the physician. The physician extracts the data from the storage, and analyzes it...

...and after the required number of nights of data collection, the patient returns the diagnostic **device** with the **stored** data. If the study will be extended, then the patient **removes** the **data** storage module and returns only the module to the physician.

The stored data are analyzed...with the therapy device for the required number of nights. During each night, the therapy **device** collects and **stores** the data as described above.

At step 164, the patient returns the therapy **device** or its data **storage** module for analysis of the stored data after the required number of nights of data...

...referred to a sleep lab for a more comprehensive study, step 160.

If the therapy **device** restores normal **breathing** patterns for the patient, the pressure data are reviewed at step 172 for the proper...

...g., eight centimeters of water pressure or less, then the patient would be prescribed conventional **CPAP** (non-self-adjusting) therapy, step 176.

While several particular forms of the invention have been...

...CLAIMS B1

1. A **breathing** **device** for optimizing the positive airway pressure to a patient, comprising:  
means (86) for applying an...

...curvature) and an ideal half sinusoidal signal around the same regression line (curvature standard),

\* a **respiratory** effort index (the ratio of peak derivative (rate of change of flow with respect to...

- ...or more of the said indices indicates a flow limitation in the patient.
2. A **breathing device** as claimed in claim 1, which includes means for decreasing the positive airway pressure whenever the said indices do not indicate a flow limitation in the patient.
  3. A **breathing device** as claimed in claim 1, in which the means for using the stored data values...
- ...calculate a sinusoidal index compares the stored data values with a sinusoidal contour.
4. A **breathing device** as claimed in claim 3, in which the means for using the stored data values...
- ...a sinusoidal index correlates the stored data values with a pure sine wave.
5. A **breathing device** as claimed in claim 1, in which the processing means includes means for calculating a...
- ...index includes a weighted coefficient having a range including a value of zero.
6. A **breathing device** as claimed in claim 1, in which the means for determining a flow limitation includes a **microprocessor**.
  7. A **breathing device** as claimed in claim 1, in which the means for storing data values includes random access **memory** associated with the **microprocessor**.
  8. A **breathing device** as claimed in claim 1, in which the means for applying an initial level of...
- ...the means for increasing the positive airway pressure includes a motor speed controller.
9. A **breathing device** as claimed in claim 1, in which the means for applying an initial level of...

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00506675

INSPIRATORY AIRWAY PRESSURE SYSTEM

DRUCKSYSTEM FUR ATMUNGSWEGE

SYSTEME DE PRESSION INSPIRATOIRE DES VOIES RESPIRATOIRES

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SPEC B	(English)	200010	14786

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INTERNATIONAL PATENT CLASS: A61M-016/00 ...

... A62B-007/04 ...

... A62B-009/00

...SPECIFICATION sleep.

In order to treat obstructive sleep apnea, the so-called continuous positive airway pressure ( CPAP ) system has been devised in which a prescribed level of positive airway pressure is continuously...

...the patient's nares and imposes the positive airway pressure on the nasal passages.

The CPAP system meets with objections from patients, however, because the patient must exhale against the positive...



...also a complaint. Also, exhaled carbon dioxide tends to remain in some nasal masks with CPAP therapy.

In prescribing CPAP therapy, it is usually necessary for a patient to spend one or two nights in a sleep treatment laboratory where it is first determined whether the patient has a **respiratory** disorder such as sleep apnea. If so, the patient is then fitted with a CPAP device whereupon the required gas pressure is determined for providing the necessary air splint to...

...patient-coupled gas delivery device for pressurizing at least a portion of a patient's **respiratory** passages, such as the nasal passages, with a breathable gas, preferably ambient air which may...phase of the breathing cycle, and initiates the pressure increase at that point in the **breathing** cycle. Alternatively, the **apparatus** determines an interval time as the point in the breathing cycle for increasing the inspiratory ...

...Fig. 10 is a schematic illustration of a pressure transducer circuit;

Fig. 11 is a **computer** program flowchart illustrating the START-UP portion of the main routine;

Fig. 12 is a **computer** program flowchart of the MAIN LOOP portion of the main routine;

Fig. 13 is a **computer** program flowchart of the VALVE STEP subroutine;

Fig. 14 is a **computer** program flowchart of the ADC interrupt;

Fig. 15 is a **computer** program flowchart of the CHECK BLOWER SPEED subroutine;

Fig. 16 is an electrical block diagram illustrating the spectral sound analysis circuit;

Fig. 17 is a **computer** program flowchart of the SOUND ANALYSIS subroutine;

Fig. 18 is a schematic block diagram of...

...airway flow, pressure and admittance, and further illustrating two admittance templates;

Fig. 20 is a **computer** program flowchart for operating the microcontroller of Fig. 18; and

Fig. 21 is a **computer** program flowchart of another program embodiment for operating the microcontroller of Fig. 18.

Fig. 22...

...the electronic components associated with the compensation embodiment of Fig. 22;

Fig. 24 is a **computer** program flowchart of the PRIMARY module for operating the compensation embodiment;

Fig. 25 is a **computer** program flowchart of the INITIALIZE module of the PRIMARY module;

Fig. 26 is a **computer** program flowchart of the EXHALE module of the PRIMARY module;

Fig. 27 is a **computer** program flowchart of the INHALE module of the PRIMARY module;

Fig. 28 is a **computer** program flowchart of the CPAP BACKUP module of the PRIMARY module;

Fig. 29 is a **computer** program flowchart of the BPM CYCLE BACKUP module of the PRIMARY module;

Fig. 30 is a **computer** program flowchart of the PATIENT CYCLE BACKUP module of the PRIMARY module;

Fig. 31A is a **computer** program flowchart of the first portion of the A/D INTERRUPT module of the PRIMARY module; and

Fig. 31B is a **computer** program flowchart of the remaining portion of

the A/D INTERRUPT module.

Detailed Description of...pillow 14 on the head of patient 36 in order to fluidically couple with the **respiratory** passages of patient 36, and preferably with the patient's nares. Nasal pillow 14 is...microcontroller 802 (Intel Type 8097BH), programmable array logic (PAL) (Type PC16L8), erasable, programmable, read-only- **memory** (EPROM) (Type 27256), address latch 808 (Type 74HC373), random access **memory** ( **RAM** ) (Type 6264P), input/output serial data interface (RS232 Type MAX232), prescription (RX) switch array 814...802 for data and address information flow with PAL 804, EPROM 806, address latch 808, **RAM** 810, and data latch 816 at the terminals as shown in Fig. 8. Fig. 8...and terminals 1, 8, and 15 are all connected to ground.

Figs. 11-14 are **computer** program flowcharts illustrating the operative program for microcontroller 802.

Fig. 11 illustrates the START-UP portion of the main routine of the **computer** program for operating microcontroller 802. After the logic low reset signal goes logic high, the...and read by way of address data bus 830. These values are then stored in **RAM** . Step 1104 also prompts microcontroller 802 to set the operating speed of blower motor 904...

...step also defines the start-up mode of the apparatus as continuous positive airway pressure ( **CPAP** ). That is to say, and as explained further hereinbelow, the program operates apparatus 10 in...of operation is set for inspiratory nasal air pressure (INAP). This was initialized in the **CPAP** mode in step 1112. During the first eight breathing cycle, the answer in step 1226...to step 1314 which retrieves the step pattern for the next blower motor step from **memory** . The program then activates the lines of bus 832 in order to send this step...

...the pressure data received from pressure transducer circuit 700, and to store this data in **memory** . Subroutine 1400 enters at step 1402 which retrieves the current data from the ADC register...conversion to produce digital data representative of the three spectrum components.

Fig. 17 is a **computer** program flowchart of SOUND ANALYSIS subroutine 1700 which is advantageously included as part of the...

...should be taken concerning the increase or decrease of the gas pressure applied to the **respiratory** passages of the patient. This determination occurs in step 1722 by use of a so-called "action table" which is a look-up table stored in **memory** using variable T as a pointer. The preferred action table is incorporated as part of...properly characterized and aspects of the respiration quantified.

Furthermore, this information can be stored in **memory** for subsequent downloading for use by a physician, for example, in diagnosing **respiratory** afflictions and efficacy of treatment. In this way the expense and time consumed in sleep...

...treating many conditions in which facilitated respiration is a factor in treatment. For example, increased **respiratory** air pressure beginning just prior to inhalation induces a deeper inhalation than might otherwise occur...

...means for patient coupling in order to impose the higher breathable gas pressure on the **respiratory** passages of the patient. The present invention, however, also encompasses a nasal mask, or a...

...to increase or decrease the pressure of the breathable gas applied to the patient's **respiratory** passages. As the detailed description reveals, however, the apparatus hereof includes the capability of varying ...

...example.

As described above, the preferred controller includes microcontroller 802 which is operated by a **computer** program. Other equivalent control means might include a custom designed chip with all functions implemented in hardware without a **computer** program.

As disclosed in Fig. 6 herein and the accompanying narrative description, it is preferred...thereby determining admittance, such problems are avoided.

As explained further hereinbelow in connection with the **computer** program flowchart of Fig. 21, it may be desirable to eliminate divider 1812 in certain...

...the inhalation portion of a single breath cycle is compared to admittance templates stored in **memory** to determine which template provides the "best fit" with the latest admittance plot. The best...

...such as raising or lowering gas pressure delivered to the patient.

Fig. 20 illustrates a **computer** program flowchart of subroutine 2000 for operating microcontroller 802 of the embodiment shown in Fig...

...the differences between the corresponding data points in array "A" and each template stored in **memory** according to the formula shown.

The program then moves to step 2010 which determines which...

...pressure, from a look-up table such as that illustrated below:

Fig. 21 is a **computer** program flowchart of module 2100 for operating microcontroller 802 in the embodiment of Fig. 18...

...airway patency is effectively quantified. That is to say, the set of templates stored in **memory** could represent a range of patencies (in percentages, for example) and the best-fit template...

...advantageous to continuously update the set of templates by storing successive admittance array data in **memory** as a new template. Additionally, certain templates could be designated as templates characteristic of wakefulness...predetermined time based upon a fixed time or based upon previous breathing patterns the preferred **breathing device** activates the electrodes to stimulate the upper airway muscles.

In this way, apneic episodes are...

...controlling and operating pneumatic system 70 of this embodiment. Controller 20 includes power supply 80, **microprocessor** 81, **microprocessor** memory 82, analog to digital (A/D) conversion circuitry 83, interface circuitry 84, serial communication port...

...and display control 87 with keyboard display panel 88 connected thereto.

Figs. 24 - 31B are **computer** program flowcharts illustrating the operation of the program stored in **memory** 82 for operating **microprocessor** 81 and thereby for operating ...variables indicated to their initial values as shown. Step 2504 then sets the pressure control **mode** to inhale and step 2506 **clears** the control **mode** flag indicating that the control mode has not been set.

Steps 2508 and 2510 then...

...The phase control flags are then reset in step 2606 and the blanking interval counter **cleared** in step 2608. The **program** then returns to the PRIMARY module.

Fig. 27 illustrates INHALE module 2700 which is entered...

...it inhalation is not detected within a time limit based on breath rate. In the CPAP mode (Fig. 28), the pressure is increased to a constant value and maintained. In the...

...breath rates, or when exhalation is sensed, whichever occurs first. Turning first to Fig. 28, CPAP BACKUP module 2800 enters at step 2802 which asks whether the backup test is true...module 3000 which enters at step 3002. This step asks whether the backup flag is clear and if yes, the program moves to step 3004 which asks whether the inhale timer count is greater than or...

...sensor value. This value is then linearized according to look-up table values stored in memory which are empirically developed for the particular patient pneumatic hose 26 being used. In practice...answer in step 3138 is yes, step 3140 sets the Prx which is the control mode to inhale. Step 3142 then clears the blank interval counter, step 3144 saves the current sample count and step 3146 clears...

...CLAIMS processing means (802) for receiving the signals and responsive thereto for determining the patient's respiratory admittance from the substantially simultaneous flow and pressure; and means (20) for controlling the pressure...

...means for storing at least one admittance template composed of a plurality of admittances in memory , means for storing a set of the patient admittances, and means for comparing the admittance...

...bases, the controlling means including means for normalizing the amplitude and time base of the respiratory admittance in accordance with the stored templates.

10. Apparatus as claimed in claim 7, in which the controlling means includes memory means for storing pressure change data in association with each of the templates, the controlling...

...as claimed in claim 1 or claim 7, in which the controlling means includes a microprocessor (802).

13. Apparatus as claimed in claim 1, in which the signal processing means (802)...

...the flows and pressures and storing admittance data representative of the admittance set in a memory device, and using the signal processing means for determining the admittances as the dividend of ...

...by pressure;  
 comparing in the signal processing means the admittance data with predetermined admittance templates stored in the memory device ;  
 and  
 determining in the signal processing means the closest match of the admittance templates with...

32/3,K/108 (Item 108 from file: 349)  
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00926148 \*\*Image available\*\*

VENTILATOR CONTROL SYSTEM AND METHOD  
SYSTEME DE VENTILATEUR PERMETTANT DE SEVRER AUTOMATIQUEMENT UN PATIENT DE  
SA VENTILATION MECANIQUE ET TECHNIQUE A CET EFFET

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VENTILATOR CONTROL SYSTEM AND METHOD  
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Detailed Description  
Claims

English Abstract

A patient **ventilator** system for automatically weaning a patient from a  
**ventilator** .

Detailed Description

A SYSTEM FOR AUTOMATICALLY WEANING  
A PATIENT FROM A **VENTILATOR** , AND METHOD THEREOF  
Cross Reference to Related Applicatio  
[00011 This application is a continuation-in...

...160.

Field of the Invention

[00021 The invention relates generally to the field of medical  
**ventilators** or, more  
specifically, to the control of such **ventilators** . @

#### Background of the Invention

[00031 A medical **ventilator** delivers gas to a patient's **respiratory** tract and is often required when the patient is unable to maintain adequate **ventilation**. **Mechanical ventilation** is the single most important therapeutic modality in the care of critically ill patients. Known **ventilators** typically include a pneumatic system that delivers and extracts gas pressure, flow and volume characteristics...

...as the condition of the patient changes. Such adjustments, although highly desirable, are difficult to **implement** with known **ventilators** because the control system demands continuous attention and interaction from the clinician.

[00041 Further, patients requiring **ventilatory** assistance must overcome airway resistance in the breathing circuit during exhalation. This resistance, combined with...

...by underlying disease processes.

#### Summary of the Invention

100051 The invention relates to a medical **mechanical ventilator device** adapted for use in weaning a patient from **mechanical ventilation**. In one embodiment, the device measures the patient's minute volume, breath frequency, and detects a patient's spontaneous **breath**. The **device** compares the patient's minute volume and the patient breath rate to a predetermined minute...

...the period of at least two breaths.

[00061 In another embodiment, the invention is a **ventilator** system adapted for use in weaning a patient from **mechanical ventilation**. The **ventilator** system comprises a pressure source in communication with the patient's **respiratory** system to provide pressure support to the patient. The **device** further comprises a **breath** frequency monitor, a minute volume flow meter, an input device, and a **data processing unit**. The **data processing unit** compares the patient's breathing frequency and patient's minute volume to the breathing frequency and minute volume entered by the clinician. Pressure support is adjusted by the **ventilator** on an intrabreath or interbreath basis.

#### Brief Descriptions of the Drawings

[00071 FIG. 1 is a block diagram of an embodiment of a **ventilator** of the invention.

[0008] FIG. 2 is a detailed block diagram of a display controller...

...diagram of an embedded controller.

[0010] FIG. 4 is a detailed block diagram of a **ventilator** pneumatic unit.

[0011] FIG. 5 is a diagram illustrating an embodiment of the adjustment of...

...[0012] FIG. 6 is pseudocode of an embodiment of a triggering algorithm used by the **ventilator** of the invention.

[0013] FIG. 6a is a pressure and flow diagram of the patient...

...patient ventilation triggering.

[00141 FIG. 7 is an illustration of a display screen when the **ventilator** control system is in the operational mode.

[00151 FIG. 8 is an illustration of a...

...FIG. 11 is a flow chart of the data structure hierarchy employed by the **ventilator** control system.

[0019] FIG. 12 is an embodiment of a flow chart of an exhalation...

...invention.

[00201 FIG. 13 is an illustration of a simulation mode display screen for the **ventilator** control system.

[00211 FIG. 14 is a functional block diagram of the simulator portion of the **ventilator** control system

[00221 FIG. 15 is an illustration of a section of the display screening ...

...waveform shaper.

[0023] FIG. 16 is an illustration of a therapy programming screen for the **ventilator** control system.

[00241 FIG. 17 is a flow chart for automatic weaning of a patient from a **ventilator** according to an embodiment of the invention.

#### Detailed Description of the Invention

[00251 1. **Ventilator** Control System - The invention features a **ventilator** control system for controlling a **ventilator** pneumatic system in a medical **ventilator**. The **ventilator** control system provides a clinician with complete control of a patient's airway flow and pressure throughout the **respiratory** cycle, and thereby enables the clinician to determine the optimal therapy for the patient. In...  
...this situation, negative pressure can be applied to the exhalation circuit of the patient's **ventilator** to reduce the ...100271 If airway pressure rises above the clinically indicated level of positive end-expiratory pressure ( **PEEP** ), the lung will be overpressurized thus the effective airway pressure throughout the expiratory cycle is titrated throughout the expiratory phase under precise algorithmic control.

The clinical benefit of a certain **PEEP** level will be diminished. Thus, the effective airway pressure throughout the expiratory cycle must remain greater than zero and less than **PEEP**.

[00281 FIG. 1 is a block diagram of a **ventilator** including a **ventilator** control system IO incorporating the features of the invention. The **ventilator** control system IO includes a display controller 12 and an embedded controller 14. The display...

...interface to the clinician 16, and the embedded controller 14 provides an interface with a **ventilator** 17 providing ventilation to a patient 20. The display controller 12 and the embedded controller 14 each include **memory** (not shown) and are electrically coupled via a shared **memory** interface 15. Data from the display controller 12 and the embedded controller 14 are stored...

...embedded controller 14 to calculate the amount of negative pressure to

be generated in the **ventilator** 17 in order to produce an airway pressure greater than zero and less than positive...

...gas delivered from the source of pressurized gas 45 through a Venturi valve within the **ventilator** 17 to produce this negative pressure. One embodiment of such a pneumatic system 41 is...

...by reference. A pressure sensor 51 measures the amount of negative pressure produced within the **ventilator** 17 and transmits these data to the embedded controller 14. These data are stored in...

...controller 12. Each of these target values is compared with a corresponding current value of **ventilatory** unit pressure, airway pressure, airway flow and airway resistance by the embedded controller 14. Upon...

...so that the pneumatic system 41 changes the amount of negative pressure produced by the **ventilator** 17. The **ventilator** 17 is in pneumatic communication with a flexible tubing 21 capable of attachment to a...

...serial number 08/352,659, incorporated herein by reference.

[0033] The safe performance of the **ventilator** 10 is enhanced by the redundancy of the two independent display controller 22 and embedded controller 30 processors, which continually check each other's performance via the shared **memory** interface 15. The embedded controller 14 communicates its status, and that of the patient, to...

...the last known good settings if communication becomes lost. The two systems which comprise the **ventilator** control system 10 give both audible and visual messages when an alarm condition exists, and...

...absence of breathing). During operation, both systems perform background tests to detect system faults. The **ventilator** provides a series of reduced operation modes to provide life support if system capability is ...flexible means to change control settings.

[0035] The display controller 12 is a powerful graphics **workstation** with hardware and software components. In one embodiment, the clinician interacts with the display controller...

...to the monitor. In one embodiment, the processor 22 is included in a single board **computer** which also includes **RAM**, an integrated high speed graphics driver, and an integrated dual port **memory**.

The display controller 12 also includes a hard disk drive 23.

[0036] While the display controller 12 provides interpretation and decision support information on the display 24, the **ventilator** 17 does not change any breath control parameters unless directed by the clinician 16. Nevertheless, the display controller 12 provides a flexible **user interface** with multiple interactive levels, from simple text menus of controls for inexperienced users, to complete...

...embedded controller 14 includes a system board 28, a real time data processor 30, a **ventilator** processor 32 and an airway processor 31.

The real time processor 30 manages sensor...

...system 19, processes measured data, performs alarm/fault detection and provides control data to the **ventilator** 17. The embedded controller 14



further receives data input by the clinician 16 and accesses...  
...system 19 relating to airway pressure, flow and resistance. A second data processor 32, a **ventilatory** unit processor, receives signals from the pressure sensor 51 in communication with the **ventilatory** pneumatic system 18. Signals from both data processors 31 and 32 are transmitted to a...

...to airway pressure, flow and resistance to preselected values and then calculating the change in **ventilatory** unit negative pressure required to affect the desired change in airway resistance.

[00391 In more detail, and referring also to FIG. 4, a block diagram of the **ventilator** 17 in communication with the flexible airway 21 that is the conduit for inhalation from...

...airway 21 to assist the patient's exhalation through the canister 49 into the medical **ventilator** 7. Pressure within the flexible canister 49 is measured by a pressure sensor 5...

...14.

[00401 Now referring also to FIG. 5 a detailed functional block diagram of the **ventilator** control system 10 is depicted. As shown, the clinician 16 manipulates a control setting slider...

...the clinician's inputs and creating 40 a breath control structure which is stored in **memory**. The display controller 12 transmits the breath control structure to the embedded controller 14 and...

...panel 36. The embedded controller 14 initially stores 44 the breath control structure in local **memory**. The ...14 re-validates 46 the settings within the breath control structure. The embedded controller 14 implements 48 the validated **breath** control structure 48 using a breath control algorithm 50 and provides signals to the pneumatic...

...panel 36 to the cause of the error and the process is terminated.

[0041] The **ventilator** control system 10 provides two independent feedback paths to assure the clinician 16 that his...

...displays 60 a series of measurements (e.g., peak airway pressure, peak airway flow, and **PEEP**) from the waveform data both numerically and graphically. Second, the display controller 12 displays 54...

...embedded controller 14 and passed directly to the display 24.

100421 One feature of the **ventilator** control system 10 is that it can be configured to provide an assisted phase...

...the accumulated volume of gas inhaled by the patient as a result of his spontaneous **respiratory** muscle activity can be monitored. To accomplish this, the sensor monitoring system 19 measures the...

...volume dynamically according to measured patient flow and pressure signals indicating the phase of the **respiratory** cycle. In particular, the embedded controller 14 may increase the trigger volume set by the...

...system 41, and not by spontaneous efforts of the patient.

100431 Another feature of the **ventilator** control system is its ability to distinguish between active inspiratory effort and passive reverse

airflow...

...until the trigger volume has been reached (Steps 320, 330).

[0046] Another feature of the **ventilator** control system is its ability to compensate for gas flow resistance into and out of...

...input device 26, the clinician 16 call set a resistance parameter of the patient's **respiratory** system to a selected value.

Alternatively, the display controller 12 may calculate a value for...

...row of touch sensitive on/off buttons 66 includes: a Power button that controls the **ventilator** control system; a Freeze button to pause the display; a Modes button to display various...

...play back a database of historical patient protocols; a 100% O<sub>2</sub> button to flush the **ventilator** with oxygen; Help and Save buttons; and an Others button to display other capabilities.

[0049] The left side of the screen includes a list of the publicly available **ventilator** control settings. ...and partially controlled by the patient, and mandatory breaths, those triggered and controlled by the **ventilator**. The ratio of the colored areas indicates the ratio of spontaneous to mandatory breathing during...

...13 the clinician selects a phase of a waveform, the display controller displays the associated **ventilator** controls for available for adjustment by the clinician.

[0056] The display controller provides cursors- 201 waveform values, positioning based on **user interface** gestures.

[0057] The background of the waveform (74, 76) includes color shading to indicate breath...

...and scale information. Redrawing these graphics as new waveform samples are displayed generally requires substantial **computer** time, and the display controller performs this function efficiently notwithstanding the complexity of the background...

...Peak Inspiratory Pressure 2 to 120 cmH<sub>2</sub>O  
Exhalation Assist 0 to 30 cmH<sub>2</sub>O/L/sec  
**PEEP** 0 to 20 cmH<sub>2</sub>O  
Inspiratory Time 0.2 to 4 sec  
Inspiratory Pause Time 0...

...to 120 cmH<sub>2</sub>O  
Oxygen Percentage 21 to 100%  
Peak Inspiratory Pressure 0 to 120 cmH<sub>2</sub>O  
**PEEP** 0 to 20 cmH<sub>2</sub>O  
Mean Airway Pressure 0 to 120 cmH<sub>2</sub>O  
Inspiratory Time 0.1...

...Alarms and Indicators

High/Low Exhaled Tidal Volume Alarm 50 to 2000 ml  
High/Low **Respiratory** Rate Alarm 2 to 150 bpm  
Low Oxygen Fresh Gas Flow Automatic, % O<sub>2</sub>  
dependent

Low...Embedded Controller - Referring again to FIG. 1, the embedded controller electronics 14 is based around **microprocessors** 31, 32. The **microprocessor** 32 is in electrical communication-with the **ventilatory**

unit 17 and the **microprocessor** 31 is in electrical communication with the sensor monitoring system 19. The embedded controller relies...

...custom printed circuit boards to perform other functions. The modules, the printed circuit boards, the **ventilatory** unit pressure processors 32 and the airway processor 31 are mounted on or connected to...

...and provides battery backup for a average of one hour. The embedded controller 14 has **microprocessor** and associated input/output hardware to provide for closed loop control of pneumatic system 41...

...Gas.  
 [0071] The embedded controller 14 communicates with the display controller 12 via a shared **memory** interface 15 at a data transmission rate exceeding 1 00K bytes per second.

[0072] 4...

...FIGS. I and I 1, the figures illustrate the data structure hierarchy for the 5 **ventilator** control system. Using an input device 26 such as the touch-sensitive display 24 within...

...13. In any case, the clinician 16 sends the new therapy control structure to the **memory** for use by the embedded controller 14 in controlling the pneumatic system 41. A therapy...A phase control structure 150 (or a cycle control) is defined as a collection of **ventilator** control settings 154 and an array of waveform. samples 156. Phase definitions and requirements for...

...to measurable system performance, and correlate closely to published descriptions of the desired behavior of **mechanical ventilators**.

- 19 [0074] More specifically, the therapy control structure 140 is a nested hierarchy of increasingly...

...control, which occurs within therapy control, which is the clinically specified therapy that drives the **ventilator** pneumatic system 41. Once each cycle, ventilation control moves from one control state to...

...from an inspiration phase to a pause phase to an exhalation assist phase to a **PEEP** phase, but these phases may be further subdivided for a finer granularity of control.

- 20...

...Within a phase, within a breath, within a mode, within a therapy, there is a **ventilator** control setting structure 154. This structure contains an array of samples that comprise a specified...

...is driven by the waveform sample specific for the cycle, and by a collection of **ventilator** control settings 154 specific for the phase. The cycle time is in milliseconds, and is...

...may be specified by the clinician and take control at the next cycle.

[0080] Each **ventilator** control setting structure 158 contains necessary and sufficient information to control one parameter...  
 ...adjusted automatically within the specified range. Each phase control structure has its own collection of **ventilator** control settings, although in practice, phases within a breath generally share the same collection.

100811...

...of hazardous conditions by permitting non-programmers to review and understand the function of the **ventilator** control system.

[0082] Several breath control structures are predefined in the embedded controller. These breath...clinician 16 entering the desired values relating to airway resistance or negative pressure in the **ventilatory** unit (Step 1). These values are then compared with data relating to airway resistance or negative pressure in the **ventilatory** unit that have been measured or calculated by the **data processing unit** (Step 2). It is then determined whether these sets of data are equal to each...

...7). It is then determined whether airway pressure is greater than zero and less than **PEEP** (Step 8). If airway pressure is greater than zero and less than **PEEP**, airway resistance is calculated and pressure in the **ventilatory** unit is measured (Step 9). After these measurements and calculations are made, the cycle recommences (Step 2). If airway pressure is not greater than zero and less than **PEEP**, it is determined whether the alarm has been overridden (Step 10). If the alarm has...

...the status of the patient's pulmonary system. The simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 in response to the set of breath parameters and the response of...

...unaffected. When the - 22 clinician 16 begins changing settings in the simulation mode, the **ventilator** control system 10 predicts the effects of the change and displays the predicted result...

...and compliance to predict the effect. The model assumes no contribution from the patient's **respiratory** muscles (i.e., a passive inspiration and exhalation cycle). The model used is.

Airway Pressure...

...Airway Flow x Airway Resistance).

I 0 [00861 A change in patient intervention in current **ventilators** typically requires multiple setting changes. Implementing such setting changes is greatly complicated by the series...

...background. Other controls are listed as active or inactive. The explicit list of active controls **clearly** delineates the exact **function** of the mode and alleviates confusion caused by inconsistent or incomplete definitions. Moreover, the simulator 212 can precisely replicate the behavior of modes on preexisting **ventilators**. The clinician 16 can make adjustments to the list of controls to accurately simulate the **ventilator** that a hospital's staff has been trained to use.

The list of controls together...

...simulated behavior can help teach the effects of various modes on patients, rather than the **ventilator** -specific mode definition.

Pi 1

[00881 As claimed in FIG. 13, while the simulator 212...a touch zone on the display 24. The processor 22 copies the selected patient protocol into **memory**. In the operational mode, the processor 22 instructs the

embedded controller 14 to simultaneously adjust...  
...protocol. In the simulation mode, the 1 5 simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 and the resulting response of the patient's pulmonary system.

[00911 The...

...00921 FIG. 14 is a detailed functional block diagram of the simulator feature of the **ventilator** control system 210. The clinician manipulates a control setting slider 216 to change or set a **ventilator** control setting. The clinician's input are stored in a **memory** 218. The simulator 220 receives the inputs and creates a phase control structure, a breath...

...24 therapy control structure) is transmitted to the embedded controller (at 224) via the shared **memory** interface. The embedded controller validates the settings within the breath control structure 226. The processor...

...data stream can be generated by sensors, which is the usual manner in which the **ventilator** operates, by the simulator 212 which uses the breath parameters and measured patient parameters to...

...to display real data, simulated data and epoch data is an important feature of the **ventilator** control system.

[0095] 9. Integrated Control/Data/Alarm. Display - Referring again to FIG. 7, patient...panel of selected targets appropriate for the range, and which, if enabled, means that the **ventilator** control system will seek to accomplish a range target goal 213 by varying the control...

...trigger for the transition fi-om variable pressure support (VPS) to assist control (A/C **pc** ) is minute volume (MV), while the trigger for the transition from assist control to variable...

...the patient, with much more power and flexibility than selecting from a set of simple **ventilator** modes preset by the manufacturer.

- 27 [01031 1 1. In another aspect, the **ventilator** , according to the invention, operates using several mode control structures in a paired configuration, which...

...Support-Variable Pressure Control (VPS-VPC), and Continuous Positive Airway Pressure-Assist Control/Pressure Control ( **CPAP** -A/C/pe). The primary mode control structure provides support to a spontaneously breathing patient. The secondary mode control structure is a mode control structure in which the **ventilator** provides Rill support to the patient with mandatory breaths. The mode transition trigger for switching...

...In one embodiment, the clinician sets a minute volume threshold, which allows the patient and **respiratory** patterns to control whether the primary or secondary mode control structure is still active. If VPC, a secondary control mode structure.

APS automates weaning of the patient from a **ventilator** and protects against patient **respiratory** failure indicated by the patient's increasing **respiratory** rate.

[0105] In a typical clinical setting, progressive withdrawal, i.e., weaning of a patient...

...VPC to obviate the necessity of frequent clinician interventions and prolonged clinician involvement with the **ventilator** weaning process. This automates the weaning of a patient from a **ventilator**. In VPC, the operating pressure range for ventilating a patient is set. The **ventilator** continuously adjusts the pressure in order to provide a minimum pressure required to deliver a - 28 set tidal volume. A breathing rate is set and the **ventilator** delivers mandatory breaths to maintain the minimum breathing rate. The patient may initiate breaths above...

...set breath rate by exerting a minimum effort, as set by the clinician, and the **ventilator** will provide the pressure support required to deliver the set tidal volume. The set tidal...

...the clinician. When the patient's minute volume is below the set MVT level, the **ventilator** remains in VPC. When the patient exerts enough effort to drive the minute volume above...

...the breathing rate is below the lower alarm limit. If either or both occur, the **ventilator** is triggered back into VPC mode.

1 5 [01081 In the APS-VPC embodiment for weaning a patient from a **ventilator** described herein, the initial pressure support level is determined by assigning the current VPC pressure support level of the patient and **ventilator** in the VPC mode, as the initial pressure support level for APS. This ensures a smooth transition for the patient and **removes** the guesswork- and the lengthy **process** of determining the pressure support level by the clinician to begin weaning of the patient from the **ventilator**. In the APS-VPC mode, the patient's effort in VPC mode determines the initial...

...be reduced.

The effect is to automate the weaning process with an automatic withdrawal of **mechanical ventilation** using a closed loop control for pressure support.

- 29 [01101 Another feature of the APS...

...0111J In the AP'S-VPC mode, the MVT level must be reached for the **ventilator** to switch between the APS mode and the VPC mode. For example, if the patient's minute volume (MV) is 10 below the MVT trigger, the **ventilator** remains in VPC, when the patient's MV is above the MVT level, the **ventilator** switches to APS mode when the patient breathes spontaneously.

[01121 In addition to monitoring and...

...limit (described below), Low Pressure Alarm Level, MVT, and Breath Rate Range. The patient begins **breathing** while the **ventilator machine** is in control mode VPC (Step 420). The starting pressure support (PS) level in VPC...

...43 0) and the patient's minute volume is greater than MVT (Step 440), the **ventilator** is switched from VPC mode to APS (Step 450).

[01141 The AP S mode detects...

...0116] The PS-DECR is set during initial step 400 by the clinician on the **ventilator** control panel.

ThePS-DECRisaRate%decrementrangingfrom0.01%to0.1%. Inoneembodiment, the clinician sets the Rate % decrement...

...clinician in Step 400.

Thus, the automatic weaning process is accomplished by automatic withdrawal of **mechanical ventilation** using a closed loop control for APS.

[0117] The patient's spontaneous breathing rate is...

Claim

CLAIMS

1 A method for automatically weaning a patient from a **ventilator**, the method comprising the steps of:  
(a) providing pressure support to a patient;  
(b) detecting...

...to the predetermined minute volume.

2 The method for automatically weaning a patient from the **ventilator** of claim 1, the method further comprising the step of. (h) decreasing the patient...

...exceeds the predetermined minute volume.

3 The method for automatically weaning a patient from the **ventilator** of claim 1, the method further comprising the step of(h) increasing the patient's...

...method of claim 1 further comprising adjusting the amount of pressure support between zero and **PEEP** . 5 . The method of claim 1 wherein the patient's pressure support level is decreased...

...from patient's spontaneous breath rate to obtain the patient's breath rate.

8 A **ventilator** system for automatically weaning a patient from a **ventilator**, comprising:  
a source of pressure in communication with the patient to provide pressure support to...

...rate range and a predetermined minute tidal volume;  
a minute volume flow meter; and  
a **data processing unit** in electrical communication with said pressure source, said breathing rate. monitor, said flow meter, and said input device, wherein, said **data processing unit** calculates an average breath rate and a current breath rate from a signal...

...and adjusts the pressure source to change pressure support in response 5 thereto.

9 The **ventilator** system of claim 8 wherein said source of pressure comprises a pneumatic system comprising a...

...pressurized gas, a rigid chamber, a flexible chamber and a Venturi valve. I 10. The **ventilator** system of claim 9 further comprising a high

speed pneumatically driven, electronically controlled proportional valve and dual Venturi systems. I 11. The **ventilator** system of claim 8 wherein said input device is a touch screen in electrical communication with a display controller processor.

12 The **ventilator** system of claim 8 wherein said **data processing unit** is a real time data processor in electrical communication with a **ventilatory** unit processor and an airway processor.

13 A method for automatically weaning a patient from a **ventilator**, the method comprising the steps of:  
providing pressure support to the patient;  
determining the patient...



32/3,K/114 (Item 114 from file: 349)  
DIALOG(R)File 349:PCT FULLTEXT  
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*Good!*

00915742 \*\*Image available\*\*

**SYSTEM AND METHOD FOR UPGRADING A MEDICAL DEVICE**

**SYSTEME ET PROCEDE DE MISE A NIVEAU D'UN DISPOSITIF MEDICAL**

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Detailed Description  
Claims

English Abstract

...operating routine executed by the controller (48). Upgrading the medical device (32) includes communicating an **external device** (34), such as a conventional **computer**, with the controller. An external access key is provided to the **external device** and compared to an internal access key provided by the medical device (32). Upgrading of...

...enabled if the two access keys match. Upgrading includes modifying or rewriting the operating routine **stored** in the medical **device** (32). A medical device (32) manufacturer, supplier, or seller controls the distribution of the external...

Detailed Description

... the medical devices to be recalled.

If a medical device uses a programmable read-only **memory** (PROM) to store the operating routine, upgrading the operating features of that device is very...

...the unit and physically replace the PROM with an upgraded PROM or other upgraded data **storage device**. Although this process is burdensome and requires that the patient forgo the use of the...

...devices and their upgraded status.

If the medical device uses an erasable programmable read-only memory (EPROM) to store the operating routine, also referred to as a flash memory, the device can be upgraded without disassembling the unit. Instead, reprogramming the EPROM can be done using any conventional reprogramming technique via a data port, which is typically provided on the external surface of the housing. While, this significantly...

...in the field, can be done by the medical device provider/dealer, if the medical device uses an EPROM storage, and if the manufacturer, supplier, or seller provides the upgraded operating routine to the medical...

...to treat a medical disorder. One such system, known as a continuous positive airway pressure (CPAP) device, supplies a flow of breathing gas at a constant positive pressure to the airway...

...OSA), Cheyne-Stokes respiration, congestive heart failure, central sleep apnea, as well as other cardio-respiratory disorders.

The ability of a pressure support system to provide a continuous pressure, as opposed...

...operating feature of the system that is determined at the time of manufacture. The specific CPAP pressure that the device is to deliver, which is typically not set when the device...

...P pressure is set to a prescription level once a patient has been prescribed the CPAP device.

Setting the CPAP pressure is accomplished, for example, by manually setting a switch, dial, knob or other input device associated with the medical device. If the CPAP operates according to an operating routine stored on an EPROM, setting the CPAP pressure can be accomplished by downloading the CPAP pressure as an operating feature directly into the controller or the memory of the medical device via a dedicated RS232 port.

A conventional ventilator, such as the ESPRITO Ventilator manufactured by Respironics of Pittsburgh, PA, is an example of a pressure support system in...

...that delivers a flow of breathing gas to the airway of a patient, including a ventilator.

A conventional ventilator is capable of operating in a variety of ventilatory modes, where each mode corresponds to a different technique by which a ventilator controls its four basic ventilator operations. These four basic operations are: 1) determining of the trigger point, which is the transition from the expiratory to the inspiratory phase of the ventilatory cycle, 2) controlling the ventilator during the inspiratory phase where the ventilator delivers the flow of breathing gas, 3) determining the cycle point, which is the transition from the inspiratory phase to the expiratory phase, and 4) controlling the ventilator during the expiratory phase.

What the ventilator does in each mode of ventilation is typically determined at the time of manufacture, so that the ventilator always operates the same way each time a particular ventilatory mode is selected. However, which ventilatory mode the ventilator is to operate in, and the particular parameters of that mode, are generally not

set when the **ventilator** leaves the factory. These operating features are set by the caregiver based on the needs of the patient when the patient begins using the **ventilator**. What the **ventilator** does in each **ventilator** mode, the selection of which mode to operate in, and the selectable parameters associated with each mode are considered the operating features of the **ventilator** for present purposes.

It is known to provide a pressure support device in which the...

...level" pressure support.

With bi-level pressure support, the patient's inspiratory positive airway pressure ( **IPAP** ), expiratory positive airway pressure ( **EPAP** ), and how the device detects and compensates for system leaks...

...to the patient based on whether or not the patient is snoring is the **Virtuosoo CPAP** family of devices manufactured and distributed by **Respironics, Inc.** This auto-titration pressure support mode...

...could occur and adjusts the pressure output to avoid this result is the **TranquilityO Auto CPAP** device, also manufactured and distributed by **Respironics, Inc.** This auto-titration pressure support mode is...

...pressure support device capable of operating in a **PAV** mode. Proportional positive airway pressure ( **PPAP** ) **devices** deliver **breathing** gas to the patient based on the flow generated by the patient. U.S. Patent... However, instead of receiving medicine, the patient receives a durable medical product, such as a **CPAP** device, to treat his or her condition. As with a medication prescription, the patient's...

...device, such as alarms, the ability to provide a time backup breath, which is a **ventilatory** breath that is delivered to the patient if he or she does not spontaneously initiate...

...support treatment or mode provided to the patient by the pressure support system, e.g., **CPAP**, bi-level, auto-titration, **PPAP**, **PAV**, or a combination thereof. While a great number of...

...the system. For example, a typical bi-level pressure support system can operate as a **CPAP** device if the **IPAP** and **EPAP** levels are the same. As noted above, a conventional **ventilator** is also typically capable of operating in one of several **ventilatory** modes.

Once a patient is prescribed a pressure support treatment, to minimize cost, he or...

...device capable of delivering bi-level pressure support to a patient who needs only a **CPAP** pressure support therapy, especially since the patient may need to be switched to a bi...

...It is also not uncommon for an **OSA** sufferer to initially be treated with a **CPAP** device, and, thereafter, switched to a bi-level device in order to increase their comfort...

...be delivered to the patient. However, other than operating the bi-level device as a **CPAP** device, as discussed above, changing the bi-level device to any other mode of pressureThe method further includes providing an **external device** that communicates with the controller, establishing a communication link between the **external device** and the controller, and inputting an external access key to the **external device**. The internal access key provided by the medical device is compared with the external access...

- ...the medical device according to an operating routine executed by the controller and (2) a **memory**, associated with the controller, that stores the operating routine. A set of operating features of...
  - ...by the medical device is associated with each set of operating features of the medical **device**. An **external device** communicates with the controller via a communication link between the **external device** and the controller. The **external device** is also adapted to receive an external access key. The controller and **external device** communicate with one another so that controller or the **external device** can compare the internal access key with the external access key. If they match, upgrading...
  - ...available to the medical device supplier, that includes the first product identifier for the medical **device** and an **external** access key associated with both the medical device and an available upgrade. The database is...
  - ...to the medical device supplier. The database includes the first product identifier for the medical **device** and an **external** access key associated with both the medical device and an available upgrade. The method includes...
  - ...the desired upgrade so that the upgrade requester can introduce the upgrade to the medical **device** if the **external** access key matches an internal access key associated with the medical device.
- In addition, the...support system, that generates a flow of breathing gas at an elevated pressure, and an **external device** 34 that communicates with pressure support system 32 via a communication link 36 for the purpose of upgrading the medical device.
- As discussed in greater detail below, **external device** 34 is preferably a conventional **computer**, such as a laptop or personal **computer**, that can be readily transported to the site where the medical device is located, such...
- ...medical system. Of course, the present invention also contemplates the opposite, i.e., bringing medical **device** to the **external device**. The present invention enables the processing components of medical device 32 to communicate with the **external device** for purposes of upgrading the operation of the medical device, for example, by downloading an...
  - ...the medical device, either in addition to or in place of the existing operating routine **stored** in the medical **device**.
- A manufacturer, supplier or seller of the medical device has the ability to control and...
- ...of each medical device under its control by limiting the ability to upgrade the medical **device** via the **external device**. According to the principles of the present invention, controlling and tracking the ability to upgrade...delivered to the patient.

For example, in a bi-level pressure support system, cycling from **IPAP** to **EPAP** and triggering from **EPAP** to **IPAP** are based on the changes in the patient's breathing cycle, which is detected by...

...support system. Still other external sensors can include EMG electrodes provided on the patient, a **respiratory** belt that measures movement of the chest and/or abdomen, and a motion sensor to...

...medical device are upgraded according to the principles of the present invention. In this embodiment, **external device** 34 includes a **processing unit** 68 that communicates with the medical device via a data port 70. **External device** also includes an input/output device 72 and the, ability to read data from a distribution medium 74, such as a floppy disk reader, a compact disc read only **memory** (CD-ROM) reader, tape drive or any other conventional data reading **device**. Of course, **external device** 34 can include other features typically associated with a conventional **computer**, such as an audio input, audio output, ports for communicating with **external devices**, such as a printer, modem or link to other communication systems via any conventional communication...48 is accomplished by coupling a communication cable between a data port 70 in the **external device** and a data port 78 provided on the medical device for this purpose. In an...

...understood, however, that the present invention contemplates any conventional technique for exchanging data between the **external device** and the medical device including a hardwired or wireless communication link.

As schematically shown in Fig. 3, controller 48 in medical device 32 includes a **memory** 80, such as a flash **memory** or EPROM. In the illustrated exemplary embodiment of the present invention, **memory** 80 is segregated in to a plurality of **memory** sections 82, each of which is individually erasable so that the entire **memory** or portions thereof can be erased and rewritten. **Memory** 80 stores the operating routine that is executed by the controller 48 each time the...

...leaks, and triggering and cycling the pressure generating system.

In one of the sections of **memory** 80, or in a portion of a section, a plurality of access key **memory** locations 84 are allocated for storing a plurality of access keys, which are discussed in greater detail below. One embodiment of the present invention contemplates providing fifteen such access key **memory** locations, of course this number can be increased or decreased so long as there is at least one access key **memory** location.

In the illustrated embodiment, a first access key "xxx" is shown stored in a first access key **memory** location 86. The access keys of the present invention are preferably a sequence of alpha-numeric characters capable of being entered and processed by a conventional **computer** processing system. It is to be understood, however, that other characters can be used in...

...character sequence, including a single character.

While Fig. 3 illustrates the remaining fourteen access key **memory** locations as being empty, it is to be understood that a default access key or...

...of the medical device are determined based on the operating routine that is stored in **memory** 80. In addition, an access key is associated with each set of operating features of...

...In effect, an access key is associated with each operating routine that is stored in **memory** 80 and capable of being carried out by the medical device. For example, in the illustrated embodiment, suppose that the internal access key "xxx" in the first **memory** location corresponds to the operating features of a **CPAP** device. Thus, in this example, the operating routine for causing the medical device to function as a **CPAP** device is stored in **memory** 80 and the access key "xxx" stored in the first **memory** location identifies the pressure support system as providing a **CPAP** mode of pressure support. Depending on the functional flexibility of the medical device and the...

...with the new set of operating features, is provided in the next available access key **memory** location. Suppose, for example, that the **CPAP** device is to be upgraded by changing the prescription pressure from its original value of...

...new internal access key, such as "yyy" is written into the next available access key **memory** location, as indicated by arrow 87. Suppose, for example, that the **CPAP** device is again upgraded by changing the **CPAP** device to a bi-level device. The operating routine is modified or completely rewritten to...

...bi-level operating features, such as "zzz" is written into the next available access key **memory** location, as indicated by arrow 89.

Each time the medical device is operated, controller 48 checks to determine whether a valid access key is stored in the access key **memory** locations. In this embodiment, if more than one access key is stored in this **memory** array, the controller will look for the access key that was the latest to be input to the medical device, for example, based on its position in the access key **memory** array. Checking to determine whether a valid access key is stored in **memory** involves generating an internal access key or retrieving an internal access key from a secure **memory** location and comparing the internal access key to the access key stored in the access key **memory** array. If these keys match, the medical device is thus capable of operating according to the operating routine stored in **memory** 80. If the keys do not match, or if there is no access key stored in the access key **memory** array, the medical device will not function, or will function at a reduced capability.

The present invention also contemplates that the access keys stored in the access key **memory** array effectively unlocks or enable additional or different operating features of the medical device, so that the particular location of the access key in the access key **memory** array is not important. In this embodiment, the present invention contemplates that the operating routine stored in **memory** 80 is capable of providing a number of different operating features. The particular operating features...

...determined based on what an access key or keys are stored in the access key **memory** array, which each access key unlocking a particular feature or set of features. In this...

...e., with the additional set of operating features, is provided in any available access key **memory** location. Suppose, for example, that the medical device is a bi-level pressure support device...

...new access key associated with this additional operating feature is added to the access key **memory** array, and the operating routine can be

modified or rewritten to cause the pressure support...

...feature only becomes enabled when the new access key is added to the access key **memory** array. Thus, the addition of access keys to the access key **memory** array effectively adds additional features to the medical device, either by unlocking existing operating features or by enabling additional programming to be stored in **memory** 90 that provides these additional features.

Again, each time the medical device is operated, controller 48 checks to determine whether a valid access key is stored in the access key **memory** locations. In this embodiment, the **controller processes** all of the access keys available for that medical device to find all of the valid access keys stored in this **memory** array. As with the previous embodiment, checking to determine whether a valid access key is stored in **memory** involves generating the internal access keys or retrieving the internal access keys from a secure **memory** location and comparing the internal access keys to the access key or keys stored in the access key **memory** array. If more than one valid access key is determined, the medical device is able...

...to not match, or if there is no access key stored in the access key **memory** array, the medical device will not function, or will function at a reduced capability.

Suppose...

...this operating feature). This requires adding an additional valid access key to the access key **memory** array that effectively allows the medical device to provide this increase pressure level. If necessary, additional programming can be downloaded from the **external device** to the controller at that time to allow the medical device to provide this additional...

...manually controlled or adjusted as done conventionally. For example, the present invention contemplates that the **IPAP** and **EPAP** levels in the bi-level pressure support device in the above example can...

...features that are actuated or enabled by the access keys stored in the access key **memory** array are additive to one another. Meaning that each operating feature added to the medical...

...features that are actuated or enabled by the access keys stored in the access key **memory** array are cumulative but not necessarily additive. Meaning that each operating feature added to the...

...set of features that can be selected by the user.

For example, the access key **memory** array may be provided with two access keys, one key allows the pressure support device...embodiment of the present invention, the controller generates the appropriate internal access key for each **memory** location or for each operating feature that the medical device is capable of providing to...

...of the access key currently residing at that location or anywhere in the access key **memory** array. Generating the appropriate internal access key for each **memory** location or for each operating feature is accomplished by running an access key determination algorithm.

Preferably, this algorithm is permanently stored in the medical device is a non-erasable memory. The details of this algorithm should not be disclosed to the users of the medical...

...medical device are not generated using an algorithm, but are read from an non-erasable memory. Of course, appropriate security measures should be taken to ensure that these stored access key...

...seller or supplier who is interested in maintaining control over the upgrading of the medical devices.

With the external device and medical device configured to communicate with one another as shown, for example, in Fig...

...73, an exemplary embodiment of which is shown in Fig.4, is provided to the external device.

In a preferred embodiment of the present invention, the algorithm for performing the medical device upgrading process is stored on distribution medium 74, which is any information storage medium magnetic, optical or otherwise, such as tape, floppy disc, memory chip, CD-ROM, and DVD, that is capable of being physically delivered to the provider...

...process, for example, by running the upgrade program stored in a CD-ROM on their computer 34. The present invention also contemplates, however, providing the algorithm for performing the medical device...

...process using other conventional data transfer methods, such as downloading the upgrade software to the external device via a LAN, WAN, or internet communication link.

The medical device upgrading process is preferably presented to the provider, via external device 34, in the form of a wizard, which is step-by-step tutorial that prompts...

...step 88 and proceeds to an introduction step 90. In step 90, the user of external device 34 is presented with an introductory display. This display preferably appears on a display terminal 90 of external device 34 (Fig. 1) or on any other output device associated with the external device. The contents of the introductory display can include any desired material, such as a welcome...

...help option, one of several, further selectable help pages can be displayed.

In addition, any computer animation or other presentation techniques can be used to present information to the user.

In...

...upgrading" also includes reprogramming of the medical device that causes the device to have fewer operating features. For example, reprogramming an auto-titration device to function as a CPAP device, or eliminating certain features, such as an auto-on, auto-off capability, or compliance...

...matter if the new operating routine replaces an existing routine or is the first routine stored in the device.

For example, the present invention contemplates that a medical device



manufacturer may supply a medical...triggering. Possible upgrades for such as device include adding a timed backup breath, adjusting the IPAP level, EPAP level, or both, reinstalling the operating routine, without making any functionality changes in...  
...backup breath, and (2) whether to upgrade the bi-level software only, without adding or deleting any operating features. The operating routine for each type of upgrade is preferably stored in a single information storage medium 74.

It should be further noted that the present invention contemplates that upgraded operating routines...

...device, the upgrading process advances to communication link establishing step 94. In step 94, the external device and the controller in the medical device attempt to establish a communication link or to...

...been established. In an exemplary embodiment of the present invention, this is accomplished by causing processing unit 68 in the external device to select the appropriate communication protocol for the medical device and to provide a device available query to an available data port on the external device. The external device waits for a reply to the query from the medical device indicating that a valid communication link between the medical device and the external device has been established.

The present invention contemplates repeating this process for each available data port...

...link with the medical device, a communication error message and/or instructions for connecting the external device to the medical device can be displayed.

The present invention contemplates that once a valid communication link is established, the external device and medical device will establish whether the medical device is a proper medical device for...

...to upgrade a bi-level device by adding a timed backup breath, but connects the external device to a CPAP device, it will not be capable of implementing the selected upgrade. In which case, a...

...all of the access key available to a medical device in a non-erasable, secure memory. In which case, step 104 involve retrieving the appropriate access key from the memory.

The present invention also contemplates that controller 48 compares the external access key with the...

...key. It should be noted that this comparison step could take place in the external device. However, this would require that controller 48 download its internal access key generated in step 104 to the external device. In the interest of keeping the internal access keys secure, it is preferable that the internal access keys not be provided to the external device.

If the internal and external access keys do not match, controller 48 notifies the external device and an error message and/or other instructions provided to the user in access key...

...and external access keys match, the upgrading process takes place in upgrade step 108 and memory 80 is rewritten or modified with a new operating routine provided by external device 34 from distribution

medium 74.

During this process, the **external device** preferably displays a status bar indicating the status of the upgrading process, for example, the amount of data or time left in the data transfer operation involved in rewriting **memory** 80.

In step 108, the next available access key **memory** location is loaded with the access key, either internal or external, from step 102. In...

...key, either internal or external, from step 102 is provided to any available access key **memory** array location. It does not matter which access key, internal or external, is loaded, since they are identical. The access key is loaded in the access key **memory** array for the reasons discussed above. Namely, each time the medical device is operated, the...

...key generate by medic device in step 104, with the keys in the access key **memory** array. There must be a match before that device will operate with the set of...

...complete and the external access key has been rewritten into the last available access key **memory** location, the process ends in termination step 110. Preferably, an "upgrade complete" display is...

...above, in an exemplary embodiment of the present invention, the upgraded operating routine is preferably **stored** on a **storage medium** for easy delivery to the provider. The external access key and the **storage medium** containing the upgraded operating routine are delivered to the provider via any conventional delivery technique...medical device is accomplished by either modifying, in whole or in part, the operating routine **stored** in the medical **device**.

It is to be understood that the present invention contemplates other techniques for altering the...

...medical device. For example, several operating routines or sub-routines can be stored in the **memory** of the medical device. These routines or subroutines can be unlocked or locked by the...

#### Claim

... an internal access key is associated with each set of operating features of the medical **device** ;  
providing an **external device** adapted to communicate with the controller;  
establishing a communication link between the **external device** and the controller;  
inputting an external access key to the **external device** ;  
comparing the internal access key provided by the medical **device** with the **external** access key; and  
enabling upgrading of the medical device by enabling the operating routine to...

...the enabling step,  
upgrading the medical device by providing a second operating routine from the **external device** to the controller, wherein the controller thereafter executes the second operating routine causing the pressure...

...claim 1, wherein establishing the communication link includes providing a hard wired connection between the **external device** and the controller.

7 The method of claim 1, wherein inputting the external access key to the **external device** includes manually entering the external access key into the **external device** via a keypad associated with the **external device**, or reading the external access key from a **memory** associated with the **external device**.

8 The method of claim 1, further comprising downloading the external access key to the controller responsive to the internal access key being input to the **external device**, and wherein comparing the internal access key with the external access key takes place in...

...time the comparing step is to be performed, or (2) stored in advance in a **memory** in the medical device and recalled from the **memory** each time the comparing step is to be performed.

10 The method of claim 1...

...the enabling step, upgrading the medical device by providing an upgraded operating routine from the **external device** to the controller, wherein the controller thereafter executes the upgraded operating routine causing the medical...

...of the medical device according to an operating routine executed by the controller and a **memory** associated with the controller that stores the operating routine, wherein a set of operating features...

...an internal access key is associated with each set of operating features of the medical device; and an **external device** (34) adapted to communicate with the controller via a communication link between the **external device** and the controller, wherein the **external device** is adapted to receive an external access key, and wherein the controller or the **external device** compares the internal access key of the medical device with the **external** access key and enables upgrading of the medical device by enabling the operating routine to...

...claim 13, wherein the controller is adapted to receive a second operating routine from the **external device** responsive to the external access key matching the internal access key, and wherein the controller

...of claim 12, wherein the communication link is a hard wired connection (36) between the **external device** and the controller.

17 The system of claim 12, wherein the **external device** includes a keypad (98) by which the external access key is manually entered into the **external device**.

18 The system of claim 12, wherein the **external device** is adapted to download the external access key to the controller, and wherein comparing the...

...time an access key validation is required. @

20 The system of claim 12, wherein the **external device** upgrades the medical device by providing an upgraded operating routine from the **external device** to the controller responsive to an upgrade being enabled, and wherein the controller thereafter executes...

...of the  
medical device according to an operating routine executed by the processing means, and  
**memory** means (80), associated with the processing means, for storing the operating routine, wherein a set...

...an internal access key is associated with each set of operating features of the medical **device** ; and  
an **external device** (34) adapted to communicate with the processing means  
via a communication link between the **external device** and the processing means, wherein the **external device** includes means for receiving an external access key, wherein the processing means or the **external device** includes means for comparing the internal access key of the medical **device** with the **external** access key and for enabling upgrading of the medical device by enabling the operating routine...

...system (38) adapted to provide a flow of breathing gas to a patient under the **control** of the **processing** means, wherein the processing means executes a first operating routine stored in the **memory** to control the operation of the pressure generating system according to a first set of...

...23, wherein the processing means is adapted to  
receive a second operating routine from the **external device**  
responsive to the external access key matching the internal access key, and wherein the processing...

...of claim 22, wherein the communication link is a hard  
wired connection (36) between the **external device** and the processing means.

27 The system of claim 22, wherein the **external device** includes a keypad  
(98) by which the external access key is manually entered into the **external device** .

28 The system of claim 22, wherein the **external device** is adapted to download the external access key to the processing means, and wherein comparing...

...time an access key validation is required.

30 The system of claim 22, wherein the **external device** upgrades the medical device by providing an upgraded operating routine from the **external device** to the processing means responsive to an upgrade being enabled, wherein the processing means thereafter...

...available to the medical device supplier, that  
includes the first product identifier for the medical **device** and an **external** access key  
associated with both the medical device and an available upgrade;  
accessing the database...

...to be upgraded and the requested upgrade;  
 providing the external access key to the medical device;  
 comparing the external access key with an internal access key associated with the medical device;  
 enabling an upgrade...device; and  
 wherein providing the external access key to the medical device comprises:  
 providing an external device adapted to communicate with the controller,  
 establishing a communication link between the external device and the medical device, and  
 inputting an external access key to the external device .

38 The method of claim 37, further comprising, after the enabling step, upgrading the medical device by providing an upgraded operating routine from the external device to the controller, wherein the controller thereafter executes the upgraded operating routine causing the medical...

...method of claim 38, further comprising providing the upgraded set of operating features to the external device from the medical device supplier.

40 The method of claim 38, wherein each internal access...

...the enabling step,  
 upgrading the medical device by providing a second operating routine from the external device to the controller, wherein the controller thereafter executes the second operating routine causing the pressure...

...claim 37, wherein establishing a communication link includes providing a hard wired connection between the external device and the controller.

46 The method of claim 37, wherein inputting an external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device , or reading the external access key from a memory associated with the external device .  
 . The method of claim 37, wherein comparing the internal access key with the external access...

...to be performed, or (2) stored in advance in the medical device and recalled from memory eachtime the comparing step is to be performed.

49 A method for a medical...

...available to the medical device supplier, that includes the first product identifier for the medical device and an external access key associated with both the medical device and an available upgrade; accessing the database...

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**A SYSTEM FOR PROCESSING AND CUSTOMIZING VENTILATOR INFORMATION**  
**SYSTEME DE TRAITEMENT ET DE PERSONNALISATION D'UNE INFORMATION DE**  
**VENTILATEUR**

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**A SYSTEM FOR PROCESSING AND CUSTOMIZING VENTILATOR INFORMATION**

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Detailed Description

Claims

English Abstract

A network compatible **user interface** system is presented for  
displaying patient medical parameters and supporting user customization  
of medical parameter...

Detailed Description

A System for Processing and Customizing **Ventilator**  
Information

This application claims the benefit of provisional U.S.

application, U.S. Serial No. 60/249,573 entitled "**Ventilator** Input"  
filed Nov. 17, 2000.

Field of the Invention

This invention is...

...processing and displaying of  
medical information, and more particularly to processing,  
customizing and displaying of **ventilator** data in a network  
environment.

Each group of the Invention...

...Such information may include

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laboratory test results, care unit data, diagnosis and treatment procedures, and **ventilator** information associated with a given patient. **Ventilators** are commonly used to ventilate a patient's lungs with breathing gas, so as to...

...breathe on his or her own is somehow impaired. In order to properly administer the **ventilator**, a caregiver must first set up various settings for the **ventilator**.

Examples of commonly required settings to control a **ventilator** include: Peak Inspiratory Pressure (PIP) setting - limiting the peak I pressure during inspiration of air; and Positive End Expiratory Pressure ( **PEEP** ) setting - limiting the peak pressure at the end of expiration of air. Many other **ventilator** settings may also be controlled, depending on the capability of the particular **ventilator**.

In addition, some **ventilators** are equipped with various sensors so that a patient caregiver may monitor the condition of the patient through the **ventilator**. Examples of commonly monitored parameters for a **ventilator** include Mean Airway Pressure (MAP) - the mean pressure measured within the airway during the breathing...

...TVi) measured volume of gas inhaled by the patient during a normal breath. Many other **ventilator** parameters may also be monitored, depending on the sophistication of the **ventilator**.

The ability to set and adjust **ventilator** parameters and parameter settings, view default parameters, and customize these parameters and settings is of...

...is highly desired.

2

Summary of the Invention

A network compatible **user interface** system is presented for displaying patient medical parameters and supporting user customization of medical parameter...

...network source.

In another aspect, the system of the present invention comprises a network compatible **user interface** system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

...shows an exemplary way of how customized parameters and settings associated with a patient and **ventilator** are displayed according to the present invention.

Detailed Description

Figure 1 is an exemplary block...

...medical devices may be connected via MIB 2; examples shown in Fig. 1 comprise a **ventilator** 6a, IV (Intravenous) Pump 8 or other medical equipment 10.

MIB 2 is typically connected...connected directly to higher

level LAN 3. For example, as shown in Fig. 1, a **ventilator** 6b and an anesthesia system 13 are connected directly to LAN 3, without the need...

...or other

types of private connection. Remote access gateway 19 may also be part of **server** 20, to be described below, instead of standing alone, as well known in the art.

6

According to the principles of the present invention, a central **server** 20 resides on LAN 3 for gathering and processing data from **ventilators** and other medical **devices** on network I for display and control. One skilled in the art can readily recognize that **server** 20 may reside at any level of the hierarchy of network 1, since all the...

...4), as well as

remote sites in Fig. 1 are interconnected together. An example of **server** 20, is a ChartAssist **server**, marketed by Siemens Medical System. The **server** may be hosted, for example, by a **computer** system that is capable of running Microsoft NT operating system.

Medical data and lab results...

...acquired and correlated with a given patient for storage in relational data base 25 within **server** 20. Data base 25 may be of the type used for storing relational data such as the Microsoft SQL **server**.

In one aspect of the present invention, a user may use a Microsoft Windows compatible **PC** 26 or Windows NT compatible **PC** 27 as shown in Fig. 1, or any other **computers** capable of running a menu generating program such as a web browser program (e.g...

...with a given patient. That is, a user may use a web browser on any **computer**, as long as a communication connection can be made to **server** 20, to make request and view information acquired and stored in data base 25. This...

...course, a user

can simply use a keyboard and/or a mouse or any other **user interface** devices to enter a user selection or request on a **user computer**, as is known in the art.

**Server** 20 is therefore capable of formatting **ventilator** data to be compatible with, for example, HTML (HyperText Mark-up Language) programming language for displaying data on a web browser. The **server** is also responsive to, for example, HTTP (HyperText Transfer Protocol) commands originated from a user...

...Figs. 2A and 2B show in flow chart form, functions that may be performed by **server** 20 in accordance with the present invention. **Server** 20 first establishes communications with devices on the network as shown in step 202. This...

...higher

application-layer protocol, as well known in the art.

Once communications are established between **server** 20



and the other devices, **server 20** starts to acquire parameters that are being monitored and settings selected for each ventilation unit (for example, 6a or 6b on network 1).

There are two different ways **ventilator** unit parameters and settings may be acquired by **server 20** from each **ventilator 6a or 8**

b. In step 204, **ventilator** data are periodically acquired from each **ventilator 6a or 6b** automatically. The periodically acquired data are then stored in a database 25 within the **server 20**. In addition, step 206 shows that a "get **ventilator** " request may be received by **server 20** from, for example, a user **computer 26** to be described in more detail later. In this case, **server 20** will instantly acquire new ventilation unit parameters and settings for the unit currently being viewed by user **computer 26**, without waiting for the current update period to expire, as shown at step 208. This "get **ventilator** " feature is particularly useful when critical, real time data are needed to make quick decisions...

...to wait for the next periodic update.

Fig. 4 shows an example of how the **ventilator** settings and parameters may be displayed on a web browser of a user **computer 26**, according to the present invention.

A user may request access to a particular **ventilator** by, for example, specifying the name of a particular patient or bed on the network (e.g., BER or 101 Bed 5) and by selecting on **ventilator** tab 301. An exemplary **ventilator** image chart display 400 is shown in Fig. 4 when the user selects chart icon 306. Exemplary image menu chart 300 displays, on the left most column, names of the **ventilator** unit parameters and settings 405 being displayed. The values of these parameters and settings are...

...time

when each value was sampled is specified in the upper row 415, A "get **ventilator** " function may be requested to obtain **ventilator 9** , data. This function may be requested by user selecting "get **ventilator** " icon 417 in Fig. 4. In an exemplary embodiment, "get **ventilator** " icon 417 will only be active and capable of being selected on user **computer 26** when the specified **ventilator** is recognized on hospital network I by **server 20**.

The displayed **ventilator** data are additionally processed by **server 20** as described in Fig. 2B. As shown in step 210 of Fig. 213, once **ventilator** unit data are obtained from a particular **ventilator** unit such as **ventilator 6a or 6b** shown in Fig. 1, either instantly or periodically as described before, **server 20** will prioritize the received ventilation unit parameters and settings for the particular **ventilator** . The **server** prioritizes the **ventilator** data in response to user request and customization of data on a web browser on, for example, **computer 26** to be described in more detail below.

In step 212, if data are obtained periodically, **server 20** will compare newly acquired parameters and settings with existing or old parameters and settings...

...New data will  
be stored in database 25 for display only if at least one **ventilator**  
setting or parameter has changed, as shown in steps 213 and 214.

This would allow...

...efficient use of database and bandwidth.

However, if data are obtained in response to "get **ventilator** "  
command, **Server** 20 will store the data, without doing any  
comparison to see whether data have changed...

...shown in  
steps 211 and 214.

10

In an exemplary embodiment, it is understood that  
**ventilator** parameters tend to change frequently (for example,  
M may changed for each inhalation by a patient), but on the  
other hand, **ventilator** settings tend to change infrequently.  
Therefore, it may be more informative and instructive for a...

...are displayed periodically (i.e., with changes  
highlighted) only if at least one of the **ventilator** settings, not  
parameters have changed. Therefore, in one alternative  
embodiment of the present invention, as shown in step 213,  
**ventilator** data will only be stored for display, if at least one  
**ventilator** setting has changed, regardless of whether any of the  
**ventilator** parameters has changed.

In step 215, **server** 20 will then allocate an attribute to  
distinguish newly acquired ventilation unit parameters and  
settings...

...and  
parameters and settings. One exemplary attribute may be display  
color. That is, when the **ventilator** image chart shown in Fig. 4 is  
requested to be displayed via **computer** 26, **ventilator** data will be  
color coded on the web browser so that the user is able...

...time.

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Referring now to Figure 3, there is provided an exemplary  
illustration of a **user interface** customization screen 300  
displayable on a web browser of a user **computer** for integrating  
data acquired from multiple sources, including manual entry,  
into a single customizable display...

...first class comprising system parameter data, obtainable for  
example, via network sources such as the **ventilator** unit or  
monitoring **device** associated with a given patient at the bedside,  
and the second class comprising user-defined...

...3, access to the customization screen  
display 300 is accomplished via user selection of the **Ventilator** ->  
Create tabs (301, 305). User acceptance of the values entered on  
the screen stores the...

...retrieval of these values for display as a single column  
entry (e.g. 4101) in **ventilator** image chart display 400 (Figure 4).

An exemplary illustration of the network compatible **user interface** system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

...previously mentioned, customization of data may be provided through a web browser on a user **computer** 12 in response to a user request via **Ventilator** -> Create tab selection for displaying customization screen 300. As shown therein, display 300 includes various **ventilator** parameters and settings for a selected **ventilator** associated with patient 3160.

Customization menu 3 00 incorporates a first window portion 3 1...and units of measure for later retrieval and display via both customization screen 300 and **ventilator** image chart display 400. This is advantageous, for example, for displaying certain parameters and settings of a ventilator or **ventilator** parameter that are not 13 recognized via the system but can be acquired at the bedside of a given **ventilator** .

Upon entry of custom parameters/settings, values, and units (332, 334, 336) and selection of...

...database 25 as default parameters that are then retrieved and displayed each time the Create **Ventilator** input screen tab (301, 305) is accessed.

In addition, web browser display generator software operates...

...user acceptance (340) by requesting and displaying the newly created/updated parameters or settings in **ventilator** image chart display 400, along with all other acquired **ventilator** parameters and settings from the network associated with the given patient.

Selection of the Set...

...current entry and update. These values may be edited and then saved as a new **ventilator** chart image entry on **ventilator** chart image display 400 (Figure 4). As previously mentioned, the Accept function 340 operates to...

...in window portions 310, 320 and 330 as a new chart 14

entry in the **ventilator** image chart display 400. More particularly, user entry and/or modification of data parameters/settings...

...control function results in a new column 4101 of parameter data generated and displayed in **ventilator** chart image display 400 corresponding to the manually entered values as well as any values maintained from the **ventilator** source. The selection of the **cancel** control function 380 operates to exit the customization screen 300 without saving the displayed data.

As shown in Figure 4, the **ventilator** chart image display 400 operates to display values of parameters identified by the user entered...

...the customization menu 300 (Figure 3) as well as from network sources such as the **ventilator** or monitoring **device** attached to the patient via the network. The **ventilator** chart image display 400 is activated in response to user selection of **ventilator** tab/icon 301 and chart sub tab 306. As previously mentioned, **ventilator** chart image display 400 is, also activated in response to selection of the accept control function 340 (Figure 3) which causes the system to obtain and display new **ventilator** data analogous to the "get **ventilator** " function previously described. Column 4101 (Figure 4) illustrates the results of such a selection, which includes manually updated setting values for **PEEP** set 3121 (value 10.7), MAP parameter 1 5 (value 22) and newly created AQ...

...new column 4101 all other settings and parameters (e.g. 3123) associated with the given **ventilator** unit 419 and patient 3160.

It is to be understood that the embodiments and variations...

#### Claim

1 A network compatible **user interface** system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

...associated with said predefined listing of parameters and settings.  
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I 1. A network compatible **user interface** system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

...claim 11, wherein said predefined list of parameters comprises parameters associated with one of (a) **ventilation** function and **ventilation device** settings and (b) blood gas characteristics.

13 The system of claim 11, further including an...

...and acquiring a customization menu defined parameter from a network source.  
19

. A network compatible **user interface** system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

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PORTABLE REMOTE PATIENT TELEMONITORING SYSTEM USING A MEMORY CARD OR  
SMART CARD

SYSTEME DE TELEMONITORAGE PORTATIF POUR PATIENT DISTANT UTILISANT UNE CARTE  
MEMOIRE OU UNE CARTE A PUCE

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PORTABLE REMOTE PATIENT TELEMONITORING SYSTEM USING A MEMORY CARD OR  
SMART CARD

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Detailed Description

Claims

English Abstract

...waveform ECG, full waveform respiration, skin temperature, and motion,  
and a connector which accepts a **memory card** or a **smart card** (20)  
for storage of the measured data. After a predetermined period of time,  
such as when the sensor band is **removed**, the **memory card** or **smart**  
**card** is **removed** and inserted into a monitoring device which reads  
the **stored** health parameter data of the subject. The monitoring device

includes a base station (30) that includes a **memory / smart card** reader and is connected to conventional phone lines (40) for transferring the collected data to...

#### Detailed Description

PORTABLE REMOTE PATIENT TELEMONITORING  
SYSTEM USING A **MEMORY CARD OR SMART CARD**  
CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part application of...

...present invention is a low cost, patient-friendly, ambulatory monitoring system incorporating a low cost **memory card** or **smart card** for the remote electronic capture of noninvasive vital signs data including, e.g., full single...

...the monitoring equipment by electrical cords, thereby limiting the patient's movement. In some prior art **systems**, the electrical cords have been **removed** and the transmissions to the monitoring equipment made using telemetry techniques; however, such systems have...

...the building wiring and the system is also designed to collect blood pressure, pulse rate, **respiratory** rate and the H<sub>2</sub>O and to relate that information to the physician via the...

...S.S. Ng describe yet another telemetry system for ECG monitoring in an article entitled '**Microprocessor** -based Telemetry System for ECG Monitoring,' IEEE/Ninth Annual Conference of the Engineering in Medicine ...

...therein describes a system for providing continuous ECG monitoring and analysis by means of a **PC AT** via wireless ...793; and 5,564,429 in which a patient wears a sensor harness including a **microprocessor** that detects potentially life-threatening events and automatically calls a central base station via radiotelemetry...

...and other costly components such as artificial intelligence software, sound and visual alarms, and a **microprocessor**, As a result, the precordial strip patch is relatively expensive to manufacture and operate ...

...unit includes a receiver, a processor for processing the received data to identify abnormalities, a **memory** for storing the sensed data, and circuitry for interfacing to a telephone line to send...

...only collected when the patient initiates the data download. Otherwise, data is lost once the **memory** in the portable unit is full. No mechanism is provided for continuously collecting data, at...sensor device attached to the patient and stores the vital signs data on a **memory card** or a **smart card** that may be inserted into the sensor device for data collection and/or transmits the...

...data logger or base station unit for processing and storage. In a first embodiment, a **memory card** is used that stores the vital signs **data** and is **removed** and its contents downloaded to a monitoring device for performing processing and monitoring functions. In a second embodiment, the electronics of the disposable sensor device are provided on a **removable smart card** -type device that may or may not have **memory** for storing the collected vital signs data. The electronics on the **smart card** may or may not include transmission circuitry for transmitting the vital signs data to a...

...sensor band with electrode patches, other sensors, and a connector dock for accepting a conventional **memory card**, such as an MMC **memory card**, for storing detected vital signs data, or a **smart card** that contains electronic circuitry and may or may not contain **memory**. Additional internal memory equivalent or discrete **memory** may also be available on the **memory card** or **smart card**. The **smart card** preferably includes the sensor band's electronics so that the cost of the disposable sensor...

...time the sensor band may be discarded and replaced by a new sensor band. The **memory card** or **smart card** is ideally designed to store all vital signs data generated by the patient during that 24 hour period. The **memory card** or **smart card** is removed from the sensor band before the sensor band is discarded, and the **memory card** or **smart card** is either mailed or carried to a remote monitoring station or...

...to the remote Monitoring station. Since the vital signs data is collected on a **memory card** or **smart card** received in the sensor band, the patient is free to move around freely while his or her vital signs are being monitored. Once the data stored on the **memory card** or **smart card** is uploaded, the **memory card** or **smart card** may be used again with another sensor band.

The second component is a base station having a **memory card / smart card**

reader for accepting the **memory card** or **smart card**, reading the vital signs data stored therein, and storing the vital signs data until the...

...and to process the stored data. For data transfer, the base station connects the **memory card** or **smart card**, via modem and land or cellular telephone line, to the remote monitoring station. Connections for...

...event flags) forwarded by the sensor band and other sensors and simply requires a standard PC running, e.g., Windows NT. ECG analysis software and a user-friendly graphical **user interface** are provided to remotely analyze the transmitted data and to permit system maintenance and upkeep...

...subject. The sensor band in accordance with the invention includes a connector that accepts a **memory card**, such as a low cost MMC **memory card**, that includes internal **memory** for storing the health parameter data produced by the sensor band, or a specially designed **smart card** that contains the signal processing circuitry (ADC, etc.) as well as any desired **memory**. The **memory card** or **smart card** is then removed and inserted into a monitoring station including a **memory card/smart card** reader which is adapted to read the health parameter data from the **memory card** or **smart card** for display or further processing. The **memory card** or **smart card** may be taken or mailed to a remote monitoring station for data download, or, conversely, the **memory card** or **smart card** may be inserted into a base station, at the patient's location for uploading the health parameter data from the **memory card** or the **smart card** to the remote monitoring station via a ...in the database with the vital signs data from a plurality of other patients. A **user interface** provides access to the vital signs data in the database for processing, medical diagnosis and/or analysis.

As noted above, the **smart card** also houses the sensor band's electronics so that the electronics may be reusable from...

- ...next. Such electronics may include a rechargeable power supply that is recharged when the memory card or smart card is inserted into the base station unit for data download. Alternatively, the power supply may reside on the sensor band (e.g., in the smart card /memory card connector) and be discarded with the disposable sensor band when the power supply is depleted...
- ...ECG, full waveform respiration, skin temperature, and motion and stores the measured data in the memory card or smart card. Auxiliary sensors are preferably provided at the base station, such auxiliary sensors including, e.g., a blood pressure cuff, a spirometer, and weight scales. Also, the user interface at the remote monitoring station may contain full ECG analysis software covering waveform measurements, interval...
- ...of cardiovascular abnormalities including hypertension, congestive heart failure, arrhythmia, silent ischaemia, and the like, and respiratory abnormalities including chronic obstructive pulmonary disease, in a presently preferred implementation of the invention, the...
- ...However, those skilled in the art will appreciate that the use of a memory card or such a smart card is not well-suited to real-time vital signs monitoring unless the smart card includes transmission circuitry. Such transmission circuitry is included in another embodiment of the invention whereby...
- ...portable data logger or base station unit for remote storage. In such an embodiment, the smart card may or may not contain memory for storing the vital signs data and may or may not include the sensor electronics. However, the inclusion of some memory on the smart card is preferred as it may act as a buffer in the event that the transmission...
- ...SPO2, skin temperature, and motion using the techniques of the invention.

FIGURE 3 illustrates the user interface to the base station unit provided in accordance with the invention.

FIGURE 4A illustrates a remote monitoring embodiment in which a server is used for data acquisition from a plurality of patients and the acquired data is...

...analysis.

FIGURE 4B illustrates a remote monitoring embodiment in which the end user has a server for data acquisition from a plurality of patients, where the end user accesses the server directly.

FIGURE 5A illustrates a general block diagram of the system electronics in accordance with a first embodiment whereby a memory card stores the vital signs data.

FIGURE 5B illustrates a general block diagram of the system electronics in accordance with a second embodiment whereby a smart card stores the vital signs data and also includes the sensor electronics.

FIGURE 5C illustrates a general block diagram of the system electronics in accordance with a third embodiment whereby the smart card includes reusable electronics for broadcasting the vital signs data to a personal



data logger where...

...general block diagram. of the system electronics in accordance with a fourth embodiment whereby the **smart card** includes the sensor electronics in addition to the reusable electronics for broadcasting the vital signs...

#### Claim

... measuring patient vital signs (health parameters) and storing the measured vital signs data in a **memory card / smart card 20** and/or transmitting the measured vital signs data to a portable data logger (not...

...connector port 13 disposed atop the signal processing circuitry 12 so as to accept the **memory card/smart card 20**. As explained in more detail below, the smart card differs from...

...in the connector and discarded with the used sensor band 10, or, alternatively, the **smart card 20** may include rechargeable battery elements. The sensor band 10 is typically removed and...

...band 10 is randomly generated and sent in a repeating cycle for easy tracking of the vital signs data stored in the memory card/ **smart card 20**. The sensor band 10 is designed such that the patient only has to prepare his or her skin...

...skin. in a position for measurement of the vital signs such as ECG. If a **memory card** or smart card. 20 rather than internal **memory** is used, the patient then inserts the **memory card/smart card 20** into the connector port 13 until (inverted exclamation mark) it engages...the sensor band 10 via a wired or wireless connection for storage on memory **card / smart card . 20**. Signal processing circuitry 12 preferably includes a microcontroller, such as an Atmel Atmega 103...

...signal), and then format the data stream into a predetermined format for storage in memory/ **smart card 20** or for transmission by a PIC microcontroller (not shown) to a transmitter of the **smart card 20** at an appropriate data bit rate. During normal operation, digital data is obtained from...

...leads of the ADC (corresponding to each of the ECG leads) every 4 msec. Preferably, a **respiratory** measurement and a battery voltage measurement are also made via the ADC every 4 msec...

...Figures 5A-5D, the functionality of the microcontroller(s) will vary depending upon whether the **smart card** is equipped only for data storage (and. hence is a **memory card**) or is also equipped for data transmission. The microcontroller(s) of the signal processing...

...with respect to Figure 5, the signal processing circuitry 12 may be included in the **smart card 20** so that the signal processing circuitry 12 may be reused from one sensor band...

...below). The signal processing circuitry

12 whether on the sensor band 10 or on the **smart card 20**, also may monitor the status of its circuitry and/or the battery level and...

...a low battery level. It should be noted that the ATmega 103 contains 4k of **RAM** for use as a stack, data buffers, and. variable storage and 128k

of programmable flash...

...to store configurable parameters used by any software implemented by the processing circuitry of the **smart card 20**. As used herein, a "memory" card differs from a "smart" card in that a **memory card** includes **memory** only, while a **smart card** also includes signal processing circuitry, such as an A/D converter and transmission circuitry...

...and no data compression. In a currently preferred embodiment, data compression is used with a **memory / smart card** capable of holding at least 96 MB of compressed data so that selected data may be captured over a 24 hour period. Of course, larger or smaller **memory** devices may be used as desired in accordance with cost and availability and the availability...

...embodiment, a base station unit 30 can only receive vital signs data from a **memory / smart card 20**. Of course, **memory / smart cards** from a plurality of patients may be inserted into the base station unit 30 to be read, and the vital signs data from each **memory / smart card 20** may be separately stored based on patient (inverted exclamation mark) identification information stored on the **memory / smart card 20** with the vital signs data. Hence, a single base station unit 30 may service...as a blood glucose meter could be connected to either connector 37 or 38. A **memory / smart card reader 39** accepts **memory / smart card 20** for reading the vital signs data stored thereon and, if rechargeable battery power is included on the **memory / smart card 20**, for recharging the battery power. During operation, the base station unit 30 reads a **memory / smart card 20** or its equivalent inserted into the **memory / smart card reader 39** and stores all data received therefrom in its internal **memory**. Preferably, the internal **memory** of the base station unit 30 is a hard disk **memory**, enabling storage of data until it is ready to be sent to the remote monitoring station 50. In a presently preferred embodiment, a **memory** having the capability of storing several days (e.g., 7 days) of data (at least 2 GB of **memory** at the sample rates described herein and assuming no data compression) is desired. Preferably...

...spirometer, weight scales, and/or blood pressure) are stored separately and aged independently in the **memory** of the base station unit 30 based on time stamps from the sensor band 10 that may be stored on the **memory / smart card 20** to enable synchronization of the time stamps of the sensor band 10 and the base station unit 30. All data is retained in the base station **memory** until either (inverted exclamation mark) it is directed to be discarded by an instruction sent from the remote monitoring station 50, or until the base station **memory** is full, at which point the earliest data is discarded first. In the preferred...

...monitoring station 50 via modem or, in an alternative embodiment, locally using a laptop or PC. In the latter case, the base station unit 30 would have an interface for the optional connection of a PC or notebook computer for the display of graphical data or for programming of the base station unit 30. The local PC or laptop could also be used for a simple video link with the remote monitoring...At the remote monitoring station 50, a physician or nurse has access to a normal PC connected by modem to the telephone line 40. Physiological monitoring software is run on this PC or on a networked system to process the data received via the modem from the base...

...or other electronic file for review by a physician. As illustrated in

FIGURE 4A, a **server** 60 may be located in the transmission lines 40 to permit data from a plurality of patients to be stored on the **server** 60 and provided to a plurality of remote monitoring stations 50 in a telemonitoring center...

...used to simply monitor a single patient or several patients from a single remote monitoring PC running the **server** 52 and physiological monitoring software. At the start of any patient study, the operator of ...

...operator will be able to view the vital signs data most recently uploaded from the **memory** / **smart** card 20, even if such data is not otherwise scheduled to be downloaded by the base...as cardiac failure, hypertension, angina, ischemia/coronary artery disease, peripheral vascular disease, acute and chronic **respiratory** insufficiency, history of recurrent arrhythmias, sub-acute patients, post-infarction patients, acute and recurrent febrile...

...invention stores the vital signs data on a memory/smart card 20 inserted into a **memory** card connector dock 13 on the sensor band 10 and then reads the stored data from the memory/smart card 20 using a **memory** / **smart** card reader 39 at a base station unit 30. Alternatively, the **smart** card 20 includes transmission electronics for transmitting the vital signs data to the base station unit...

...Microcontroller 64 also provides the necessary supply and drive signals to the electrodes 62. A **memory** card connector dock 13 accepts the **memory** card 20 and includes a connector 13' which allows the conditioned vital signs data 66 from the microcontroller 64 to be stored on the memory card 20. **Memory** card 20 thus receives data from the microcontroller 64 including multiplexed sensor signal sample data. The sensor band 10 continuously stores the data 66 including vital signals data on the **memory** card 20, and the contents of **memory** card 20 are later given/mailed to the operator of the monitoring station 50 or inserted into **memory** card reader 39 of the base station unit 30 for later uploading to...

...from the ECG and respiration signals, respectively. The received vital signs data is accumulated in **memory** 72 where it is stored until a remote monitoring station upload is initiated, at which...  
...station 50 then processes and displays the received vital signs data using a conventional personal **computer** 78, as will be described in more detail in the following section. In a preferred...data be compressed for faster data downloading to the remote monitoring station 50. Alternatively, the **memory** card 20 may be mailed or returned to the remote monitoring station 50 for reading...

...memory/smart card 20 may function as an on-body data logger preferably having enough **memory** to last 24 hours ((inverted exclamation mark).e., until the sensor band 10 is...

...be used with the next sensor band 10 while the contents, of the first **memory** /smart card 20 are being downloaded. This embodiment simplifies the downstream electronics and removes the...

...freedom of movement is traded off against an increase in size and weight of the **memory** card 20 (approximately 2.5 times the size of a wireless circuit at around approximately...including microcontroller 64 and the associated battery/power components may be included in the **smart** card 20' as shown in Figure 5B. In this embodiment, the signal

processing circuitry 12 as well. as the **memory** of the smart card 20 may be reused by respective sensor bands 10, thereby...

...bands 10. As noted above, the battery/power components need not be on the **smart card** 20, but may be included in the sensor band 10. This embodiment also has...

...embodiment illustrated in Figure 5C, the signal processing circuitry 12 may be included on the **smart card** 20 along with microcontroller circuits and transmitter elements that transmit the vital signs data over ...

...Though not shown, the base station unit 30 in this embodiment may also have a **memory / smart card** reader 39 as in the embodiments of Figures 5A and 5B. This embodiment allows for...

...circuitry including microcontroller 64 and the associated battery/power components may be included on the **smart card** 20... along with the signal transmission circuitry as shown in Figure 5D. The embodiment of...

...of Figure 5C. As noted above, the battery/power components need not be on the **smart card** 20... but may be included in the sensor band 10. In the embodiments of...

...way transmission for the acquisition of live data). These embodiments allow the electronics on the **smart card** 20 or 20... to be minimized to a much smaller weight and area (approximately 12...

...Accordingly, it is currently contemplated that at least 96 Mbytes will be required for the **memory card** 20 or **smart card** 20 in the embodiments of Figures 5A and 5B or for the portable data logger...

...could allow for a much higher level of compression with a corresponding, cost saving in **memory** size. Also, the transmission circuitry of the **smart card** 20 or 20... preferably inserts an identifier stored in an onboard EEPROM in order to... illustrates an embodiment of FIGURE 413 in which the remote monitoring station 50 includes a **server** 52 for managing the processing of the vital signs data received from the base station...

...functional arrangement would be utilized for implementing the embodiment of FIGURE 4A except that the **server** would be located in a separate physical unit or at a remote location. Each of...

...the base station-remote monitoring station communications protocol described in the previous section.

The main **user interface** 84 provides all normal user interaction with the remote monitoring station 50. In the preferred embodiment, the **user interface** 84 has no customization or set-up options; all such functionality is provided by the system maintenance **user interface** 86. **User interface** 84 is designed to interface with the user manager 90, which maintains current state information...

...this is felt necessary (e.g. the schedule manager 82 may interface directly). Preferably, the **user interface** 84 embeds instances of the graphics control process 92 for controlling the display of graphical data.

The system maintenance **user interface** 86 provides control over any configurable parameters. In the preferred embodiment, an interface to the audit log 88 is provided from the system maintenance **user interface**

86 so that the operator may view the audit log. Preferably, settings that cause changes...

...that the user does not need to keep switching between the two modes. System maintenance **user interface** 86 also interfaces with the user manager 90, which maintains state information and the...  
...state information about a single Client user session. The coupling of user manager 90 to **user interface** 84 depends on the implementation methods actually used. Preferably, user manager 90 obtains a user name and password, from the user and then activates either the **user interface** 84 or the system maintenance **user interface** 86 depending on the privilege level of the user. User preferences and other settings are...a single phone line. Therefore, this aspect of the system will behave, independently from the **user interface**.  
Generally, download schedule manager 82 will use the case properties to download data from the...

...monitoring station 50. In addition, it is preferred that any data download shall not cause data to be removed from the base station unit 30 such that the same or additional data could be...

...database 110. - 34

#### 4 Security

For purposes of accountability, and to simplify the **user interface** for normal users, it (inverted exclamation mark)S necessary to identify all users with a...

...audit record should be kept in audit log 88 (FIGURE 6) separate from the patient **database** 110. **Clearing** the audit log 88 will only be possible by administrator level users. A checksum based...export/import;  
- 35

12 Data back-up/restoration/archiving; and

13 Adding/removing users.

B. **User Interface** to Monitoring Software

FIGURE 7 illustrates a diagram of the top level uses of the...

...and shutting down/logging off the remote monitoring station

50 The use cases and the **user interface** of the remote monitoring station 50 used for implementing such use cases will be described...of the remote monitoring station software will now be described with respect to the **user interface** screen displays of FIGURES 11 and 12. To use the remote monitoring station software...in patient compliance as compared to current telemetric monitoring methods. Though the use of a **memory** card 20 or smart card 20' without transmission circuitry in accordance with the invention is not conducive to real-time monitoring, the use of a **memory smart** card 20 is particularly well suited to non-real-time - 44 monitoring as when monitoring...

...embodiment without materially departing from the novel teachings and advantages of the invention. For example, **data processing** such as ECG analysis could be performed at the base station unit 30 and only...

...to the patient for use in downloading software and uploading data from/to an Internet **server** for connection to a predetermined remote monitoring station connected to a designated node on the...

...were still required, connections could be built into the hardware of the

patient's, personal **computer** . All such modifications are intended to be included within the scope of this invention as...

...A health parameter data collection and monitoring system, comprising:  
at least one of a memory **card** and a **smart card** which stores said health parameter data;  
a sensor band and having a sensor assembly for...

...health parameter of the subject, said sensor band further comprising a connector which accepts said **memory card** or said **smart card** for storing said health parameter data produced by said sensor band; and  
a monitoring station including a **memory / smart card** reader which (inverted exclamation mark)S adapted to read said health parameter data from said...memory/smart card reader and a memory which stores health parameter data read from said **memory card** or said **smart card** until at least one of said health parameter data and...

...energy to said sensor band. -47

14 A system as in claim 1, wherein said **smart card** is rechargeable.

15 A system as in claim 10, wherein said **memory card** or said **smart card** is adapted to store at least 24 hours' worth of said health parameter data.

16...

...band comprises signal processing circuitry that processes said health parameter data for storage on said **memory card** or said **smart card** .

17 A system as in claim 16, wherein said **smart card** further comprises FM signal transmission circuitry, said system further comprising a data logger in range...

...be downloaded to said monitoring station.

18 The system as in claim 1, wherein said **smart card** is adapted to receive health parameter data from at least a second sensing device.

19...

...subject motion.

20 A system as in claim 17, wherein at least one of said **smart card** and said data logger comprises data compression circuitry that compresses received health parameter data.

21...

...said FM signal transmission circuitry inserts an identifier that identifies at least one of said **smart card** and said sensor band as the source of the transmitted health parameter data.

22 A system as in claim 10, wherein said **smart card** comprises signal -48 processing circuitry that processes said health parameter data for storage on said memory **card** or said **smart card** .

23 A system as in claim 22, whercin said **smart card** further comprises FM signal transmission circuitry, said system further comprising a data logger in range...

...monitoring station.

24 A system as in claim 23, wherein at least one of said **smart card** and said data logger comprises data compression circuitry that compresses received health parameter data.

25...

...said FM signal transmission circuitry inserts an identifier that identifies at least one of said **smart card** and said sensor band as the source of the transmitted health parameter data.

26 A health parameter data collection and monitoring system, comprising: at least one of a **smart card** and a **memory card** which stores said health parameter data; a sensor band having a sensor asseinsky for...

...health parameter of the subject, said sensor band further comprising a connector which accepts said **memory card** or said **smart card** for storing said health parameter data produced by said sensor band; a base station unit including a **memory / smart card** reader and a memory which stores health parameter data read from said **memory card** or said **smart card**; and a remote monitoring station connected to said base station unit via a communications link, said remote monitoring station uploading, via said communications link, health parameter data stored in said **memory** of said base station unit. -49

27 A system as in claim 26, whercin said...said health parameter data and stores a summary of said physiological parameter data in said **memory** for transmission to said remote monitoring station.

28 A system as in claim 26, wherein said **memory** of said base station unit is a rolling first-in-first-out (FIFO) **memory** which stores said health parameter data irrespective of whether said health parameter data has been...

...input connection for accepting auxiliary data input from an auxiliary health parameter sensor and said **memory** stores said auxiliary data input for transmission to said remote monitoring station.

30 A system...

...and ages independently said auxiliary data and said health parameter data while stored in said **memory** of said base station unit.

32 A system as in claim 29, wherein said auxiliary...

...indicates an event condition and stores event data indicating a significant physiological event in said **memory** when an abnormal physiological condition is detected.

34 A system as in claim 33, whercin...

...and ages independently said auxiliary data and said health parameter data while stored in said **memory** of said base station unit.

35 A system as in claim 29, wherein said base...

...said auxiliary data and stores a summary of said physiological auxiliary parameter data in said **memory** at said base station unit for transmission to said remote monitoring station.

36 A system...

...performs ECG analysis of said health parameter data and stores ECG analysis data in said **memory**.

37 A system as in claim 35, wherein said **memory** separately stores said health parameter data and said calculated physiological auxiliary parameter data.

38 A...

...35, wherein said remote monitoring station comprises a monitoring station processor and a monitoring station **memory**, said monitoring station processor performing ECG analysis of said health parameter data and stores ECG analysis data in said monitoring station **memory**.

39 A system as in claim 35, wherein said remote monitoring station comprises a monitoring station processor and a monitoring station **memory**, said monitoring station processor performing **respiratory** rate analysis of said health parameter data and stores **respiratory** rate analysis data in said monitoring station memory.

A system as in claim 35, wherein said remote monitoring station comprises a monitoring station processor and a monitoring station **memory**, said monitoring station processor performing SpO<sub>2</sub> analysis of said health parameter data and stores SpO<sub>2</sub> analysis data in said monitoring station **memory**.

41 A system as, in claim 29, wherein said remote monitoring station includes an interface...

...indicating an event condition and storing event data indicating a significant physiological event in said **memory** when said received health parameter data is outside said predetermined ranges or when an abnormal physiological condition is detected.

43 A system as in claim 42, wherein said **memory** of said base station unit is a rolling first-in-first-out (FIFO) **memory** which stores at least said health parameter data irrespective of whether said health parameter data...

...monitoring station.

44 The system of claim 43, wherein said rolling first-in-first-out **memory** further stores event data irrespective of whether said event data has been transmitted to said...units.

54 A system as in claim 53, wherein said remote monitoring station includes a **server** which controls the receipt and storage of health parameter data from said at least two...



...transmission to said portable data logger.

58 A system as in claim 56, wherein said **smart card** comprises signal processing circuitry that processes said health parameter data for transmission to said portable...

...of at least one health parameter of the subject; providing at least one of a **memory card** and a **smart card** for insertion into a connector of said sensor band, said **memory card** adapted to receive said health parameter data from said sensor assembly; and providing a monitoring station including a **memoryIsmart card** reader which is adapted to read said health parameter data from said **memory card** or said **smart card** for storage in a (inverted question mark)atabase.

60 A method as in claim 59...

...of deten-nining whether the subject moved during a measurement of said health parameter **data** and **deleting** or ignoring health parameter **data** collected during a time the subject moved if such movement may have corrupted the...

...data indicative of values of at least one health parameter of the subject; providing a **smart card** for insertion into a connector of said sensor band, said **smart card** adapted to ...including a receiver which is adapted to receive said transmitted health parameter data from said **smart card** for storage in a database.

72 A method as in claim 71, wherein said **smart card** comprises FM signal transmission circuitry, said method comprising the farther steps of providing a data...

...transmitting an identifier with said health parameter data that identifies at least one of said **smart card** and said sensor band as the source of the transmitted health parameter data.

75 A...

...that the drug/therapy has been provided and when; inserting at least: one of a **memory card** and a **smart card** into said sensor band, said **memory card** or said **smart card** storing said health parameter data and said event data; removing said **memory card** or said **smart card** after a predetermined period of time; and inserting said **removed memory card** or **smart card** into a remote monitoring station that captures said health parameter data and said event data...

32/3,K/132 (Item 132 from file: 349)  
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00851312 \*\*Image available\*\*

**METHOD AND APPARATUS FOR DETERMINING RESPIRATORY SYSTEM RESISTANCE  
DURING ASSISTED VENTILATION**

**PROCEDE ET APPAREIL PERMETTANT DE DETERMINER LA RESISTANCE DU SYSTEME  
RESPIRATOIRE LORS D'UNE VENTILATION ASSISTEE**

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**METHOD AND APPARATUS FOR DETERMINING RESPIRATORY SYSTEM RESISTANCE  
DURING ASSISTED VENTILATION**

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Detailed Description

Claims

English Abstract

Method and apparatus are described for determining **respiratory** system  
resistance (R) in a patient receiving gas from a **ventilator**. A negative  
pulse in the pressure and/or flow output of the **ventilator** during  
selected inflation cycles is generated and Paw, V dot and V are measured  
at...

Detailed Description

TITLE OF INVENTION

**METHOD AND APPARATUS FOR DETERMINING RESPIRATORY  
SYSTEM RESISTANCE DURING ASSISTED VENTILATION**

FIELD OF INVENTION

This invention relates to **mechanical ventilation**, and in particular,  
to assisted ventilation and the determination of **respiratory** system  
resistance.

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US FILE  
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26 APRIL  
2000

see U.S.  
CLAIM

#20

#### BACKGROUND TO THE INVENTION

There are currently no reliable, clinically available, non-invasive means to estimate **respiratory** resistance (R) during inspiration in **mechanically ventilated** patients who have spontaneous **respiratory** efforts. Calculation of resistance requires knowledge of the force applied to the **respiratory** system which, in such patients, includes a component related to pressure generated by **respiratory** muscles ( $P_{mus}$ ).

This component continuously changes during the inflation phase and cannot be estimated without prior knowledge of **respiratory mechanics**. Furthermore, to isolate 1/5 the component of total applied pressure that is dissipated against...

... $P_{el}$ ...), it is necessary to subtract the pressure used against the elastic recoil of the **respiratory** system. This requires knowledge of passive **respiratory** elastance (E) which is also difficult to determine in the presence of unquantifiable  $P_{mus}$ . At...

...catheters, which add another invasive intervention to already much instrumented patients, or by elimination of **respiratory** muscle pressure output with paralysis, or hyperventilation (controlled **mechanical ventilation**, CMV). The latter entails additional personnel time and does not lend itself to frequent deten...

...prevailing R values, a feature that is of particular utility in pressure assisted modalities of **ventilatory** support (Pressure Support Ventilation, Proportional Assist Ventilation).

In US patent 5,884,622 (Younes), assigned...

...types of transient changes in flow in the course of the inflation phase of the **ventilator**.

The changes in airway pressure ( $P_{aw}$ ), flow (V), and volume (V) during these transient flow...

...of data points from each breath, greatly increases the computing and storage requirements of the **computer** used to process the information to provide the value of R. This requirement adds further strain on the extensive and highly complex operations carried out by modem, **computer** controlled **ventilators**.

#### SUMMARY OF INVENTION

The method and apparatus described in detail herein in accordance with the...

...in US patent 5,884,622. As indicated above, the main obstacle to determining **respiratory** resistance during assisted ventilation is the uncertainty about what happens to  $P_{mus}$  during interventions in...

...that is clinically useful, such as in assisted ventilation

In accordance with the present invention, **respiratory** resistance (R) is determined while allowing for the presence of pressure generated by **respiratory** muscles ( $P_{mus}$ ) but without requiring knowledge of its actual value or an accurate I/O value of passive **respiratory** elastance (E).

In accordance with one aspect of the present invention, there is provided a method of determining **respiratory** system resistance (R) in a patient receiving gas from a **ventilatory** assist device (**ventilator**), comprising estimating the flow rate (V) and volume (V) of gas received by the patient from the **ventilator**, estimating pressure  $P_5$  near the airway

of the patient ( $P_{aw}$ ), generating a signal that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles, measuring  $P_{aw}$ ,  $\dot{V}$  and  $V$  at a point ( $T_0$ ) near the...nining R.

In accordance with another aspect of the present invention, there is provided an **apparatus** which interfaces with **ventilatory** assist devices ( **ventilators** ) deterriuning **respiratory** system resistance ( $R$ ), comprising a flowmeter, with associated electronic circuitry, that estimates the flow rate...

...from above mentioned circuitry and which is also connected to the control system of the **ventilator** , comprising.

- circuitry that generates an output that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles;

- circuitry that measures  $P_{aw}$ ,  $\dot{V}$  and  $V$  at a point ( $T_0$ ...

...OF THE INVENTION

According to the equation of motion, the total pressure applied to the **respiratory** system ( $P_{app}$ ) is dissipated against elastic, resistive and inertial opposing forces. Thus.

$P_{aw} = P_{el} + P_{res}$ ...

...change in flow in  $\dot{V}$  (  $\dot{V}$  ) and inertia ( $I$ ). Because  $I$  of the **respiratory** system is very small ( $I \approx 0.02 \text{ cmH}_2\text{O/l /sec}^2$ ),  $P_{el}$ ,  $r$  can be ignored...

...long as measurements are made at relatively low  $\dot{V}$  (e.g.  $< 10 \text{ l/sec}^2$ ). In **mechanically ventilated** patients,  $\dot{V}$  may exceed this level only in the first about 1 00 1 5...

...Piner.

During assisted ventilation,  $P_{app}$  is made up of two components, one provided by the **ventilator** ( $P_{aw}$ ) and one provided by the patient ( $P_{mus}$ ). Thus,  $P_{app} = P_{aw} + P_{mus}$ . With this...

... $P_{mus}$  and in volume can be ignored and  $P_{aw}$  becomes  $P_{res}$ . In practice, however, during **mechanical ventilation** it is not possible to instantly reduce flow from one value to another relatively stable  $\dot{V}$  and  $\dot{V}/\dot{V}$  (at are acceptably small). Even if flow exiting the **ventilator** is altered suddenly, a finite time must elapse before the flow to the patient stabilizes...

...of a known value of  $E$ , a default value, representing, for example, average  $E$  in **ventilator** dependent patients, can be used without much risk of significant errors. It should also be...

...one example will be illustrated which represents the most widely accepted behavior of  $R$  in **mechanically ventilated** intubated patients, namely that  $R$  is minimally (or not at all) affected by volume but default value (e.g.  $28 \text{ cmH}_2\text{O/l}$ , representing average  $E$  in **mechanically ventilated** patients (personal observations), may be used. Resistance can be obtained from the above equation (9...

...value.

Potential Sources of Errors and Approaches to Minimize such errors.

1) Measurement noise: In **mechanically ventilated** patients, the  $P_{aw}$  and  $\dot{V}$  signals are subject to noise from multiple sources. These include ...

...liquid in the tubing and oscillations or vibrations in the flow delivery system of the **ventilator**. The noise in the  $P_{aw}$  signal may be in phase or out of phase with...

...flow, and vice versa. Also, such differences convert the relatively innocuous inphase oscillations originating from **ventilator** flow delivery systems to potentially more serious out-of-phase oscillations in  $P_{aw}$  and flow...related to extrapolation of the  $P_{mus}$  trajectory.

These are potentially the most serious particularly when **respiratory** drive, and hence  $AP_{mus}/A_t$ , is high. The proposed approach involves the assumption that  $AP_{mus}$ ...

...is easy to accomplish during Proportional Assist Ventilation (PAV). In this mode, the end of **ventilator** cycle is automatically synchronized with patient effort and is constrained to occur during the declining...

... $P_{mus}$ . So long as pulses are not delivered in the last fraction (ca 30%) of **ventilator** TI, one is assured that Tj termination did not occur within the pulse. With pressure...

...example, if a perturbation occurs regularly every 5 breaths, the patient may alter his/her **respiratory** output every fifth breath, even before the pulse is initiated. The occurrence of anticipatory responses...

... $P_{mus}$ , independent of changes in electrical activation, through the operation of the intrinsic properties of **respiratory** muscles (force-length and force-velocity relations). An important contribution from either of these responses...my practical experience favors the extrapolation technique. Thus, it was found in studies on 67 **ventilator** dependent I O patients that the results of the extrapolation approach are in closer agreement...reflects the actual system used to validate the inventive procedures of the invention in 67 **ventilator**-dependent patients. The preferred embodiment has several components. Although in Figure 2, these components are...

...components, in actual practice all three components can be incorporated within a single unit (the **ventilator**).

A gas delivery unit I O is a **ventilator** system that is capable of delivering O proportional assist ventilation (PAV). A variety of mechanical...

...to the assignee hereof and the disclosure of which is incorporated herein by reference. The **ventilator** illustrated in the preferred 5 embodiment consists of a piston 12 reciprocating within a chamber...

...A potentiometer 20 measures the piston displacement which corresponds to the volume change during the **ventilator** cycle. After certain corrections related to leaks and gas compression, this signal conveys the amount...

...controller 28 receives the flow and airway pressure signals. These can be obtained directly from **ventilator** outputs of flow (V) out and airway

pressure (P). Alternatively, flow and airway pressure are...

...patient flow and airway pressure, reasonably accurate estimates can be obtained from sensors within the **ventilator** body, remote from the patient, after I O allowances are made for tube compression. The...

...clock circuit allows flow, pressure and volume to be sampled at precise intervals. The basic **computer** is an MC68HC16 with AM29F010 ROM and KM68-1000 **RAM**. A preferred embodiment of the master **computer** program includes several functions as follows.

(1) A function to identify the beginning of inspiration...perturbations can be slowed down, as, for example, when the clinical condition is fairly stable. **Clearly** other **methods** of ensuring that pulses are applied at random intervals are possible.

Pulses may also be...

...sampled at about 6 msec or other convenient time interval, to be stored in data **memory** over the entire period of inspiratory flow in breaths receiving pulses.

(5) A subprogram that...

...and volume at these four time points for each pulsed breath.

(7) A subprogram that **deletes data** points that fall outside the normal variability of the data. This subprogram also identifies breaths subjected to a pulse perturbation where certain criteria are not met. **Data** related to these observations are **deleted** from the tables.

(8) A **program** that determines the amplitude of pulses to be delivered. This is I O an...

...pulse is increased again. Conversely if the trough results in zero flow with resetting of **respiratory** cycle, the amplitude of the pulse is decreased. The intent of this subprogram is to...

...the negative pulses is close to, but not zero.

(9) A subprogram that causes early **data** to be **deleted** as new **data** are acquired, leaving only the results of a specified number of pulses (e.g. last 20 pulses) in the tables.

(10) A statistical subprogram to calculate the values of **respiratory** system resistance (R) from equations 8, 8a, 8 inter, 8a inter, 8 (bextra) and 8a...

...illustrated, the same functions performed by this micro controller can be incorporated into a resident **computer** within the **ventilator** by suitable programme.

It is also recognized that the application of this technology is not...

...the specific piston-based PAV delivery system used in the above preferred embodiment. All commercial **ventilators** suitable for use in the Intensive Care Unit are capable of providing outputs related to...

...well within the skill of anyone experienced in the art. It is also evident that **microprocessors** and electronic accessories other than those described in the preferred embodiment can be utilized to... transient perturbations in pressure and flow are produced by

a mechanical system independent of the **ventilator** itself and incorporated in the external tubing.

7) Where transient perturbations in pressure and flow...

...sake of determining resistance, are applied during modes other than PAV, including volume cycled assist, **CPAP** mode, pressure support ventilation or airway pressure release ventilation, whereby perturbations are produced by superimposing...

...TI.

#### SUMMARY OF DISCLOSURE

In summary of this disclosure, the present invention provides method and **apparatus** to determine **respiratory** resistance (R) during assisted ventilation of a patient in a unique and simplified manner. Modifications ...

#### Claim

I . A method of determining **respiratory** system resistance (R) in a patient receiving gas from a **ventilatory** assist device ( **ventilator** ), comprising:  
estimating the Dow rate (V) and volume (V) of gas received by the patient from the **ventilator** ;  
estimating pressure near the airway of the patient (Paw);  
generating a signal that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles;  
measuring Paw, V and V at a point (To) near the...

...nination of R.

20 The method of any one of claims I to 19 including **deleting** early **data** as new **data** are acquired and reporting the results of the determination of R for a specified number...

...Paw or'@ is produced by an electromechanical system attached to the external tubing of the **ventilator** as opposed to directly interfacing with the **ventilator** control system.

23 The method of any one of claims I to 22, wherein the...

...resistance values are used in closed loop control of an assist level provided by the **ventilator** .

24 An **apparatus** which interfaces with **ventilatory** assist devices ( **ventilators** )

determining **respiratory** system resistance (R), comprising:  
a flowmeter, with associated electronic circuitry, that estimates the flow rate is also connected to the control system of the **ventilator** , comprising:  
- circuitry that generates an output that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles;  
circuitry that measures Paw, V and V at a point (To...

...by regression analysis performed  
on the results of two or more pulses applied in separate **breaths** .  
33 The **apparatus** of any one of claims 24 to 31 wherein a default  
elastance value (E) is...

...random intervals.

39 The apparatus of any one of claims 24 to 38 including a **user  
interface** that  
permits the user to select one or more pulse characteristics.

40 The apparatus of...

...analysis.

43 The apparatus of any one of claims 24 to 42 including algorithms which  
**delete** early **data** as new **data** are acquired, reporting the results  
of a specified number of Pulses. 44- The apparatus of...

...or V are produced by an electromechanical system attached to The  
external tubing of the **ventilator** as opposed to directly interfacing  
with the ventilator  
control system.

47 The apparatus of...



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DIALOG(R)File 349:PCT FULLTEXT  
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00800345 \*\*Image available\*\*

**APPARATUS FOR CONTROLLING A MEDICAL DEVICE**

**PROCEDE ET APPAREIL PERMETTANT DE SURVEILLER ET COMMANDER UN DISPOSITIF  
MEDICAL**

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LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM  
TR TT TZ UA UG UZ VN YU ZA ZW

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... **A62B-007/00 ...**

... **A62B-009/00 ...**

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Fulltext Availability:

Detailed Description

Claims

English Abstract

...32, 32'), such as pressure support system, and a method of  
communicating with such a **device** using an information **storage device**  
(34, 34'). The information **storage device**, in one embodiment, is  
adapted to be provided in a slot (70) in the medical...

...for controlling the operating of the pressure support device can be read

from the information **storage device** , information regarding the usage and/or operation of the pressure support device can be written to the information **storage device** , or both operations can be performed.

#### Detailed Description

- ... a medical device, and, in particular, to a medical device, such as a pressure support **system** , in which a **removeable** information **storage device** selectively inserts into a slot provided in the medical device for monitoring the use or...
- ...are well known. For example, it is known to use a continuous positive airway pressure ( **CPAP** ) device to supply a flow of breathing gas at a constant positive pressure to the...
- ...the flow of breathing gas effecting splints the airway, thereby preventing its collapse. Examples of **CPAP** devices are the REMstaro and Solo® family of pressure support devices manufactured and distributed by Respironics, Inc. of Pittsburgh, PA.
- In a typical **CPAP** device, the operating parameters, such as output pressure, and, hence, the flow of fluid delivered...
- ...level to be changed by an authorized caregiver or technician, so that a commonly designed **CPAP** device can be used to provide a pressure support therapy to patients requiring different pressure...
- ...as the needs of that patient change, without having to replace the patient's existing **CPAP** device with a new **CPAP** device. Of course, modifying the prescription level should only to be done under a careoriver...
- ...tightly controlled to prevent unauthorized tampering or inadvertent modification of the operating parameters of the **CPAP** device.
- It is also known to provide a positive pressure therapy in which the pressure...
- ...breathing gas delivered to the patient varies with the patient's breathing cycle. A conventional **ventilator** , such as the Esprit® **Ventilator** , also manufactured by Respironics, is an example of a pressure support or **ventilator** system in which the pressure of gas delivered to the patient varies between inspiration and...
- ...that delivers a flow of breathing gas to the airway of a patient, including a **ventilator** .
- It is also known to vary the pressure delivered to the patient between inspiration and...
- ...pressure support.
- With bi-level pressure support therapy, the patient's inspiratory positive airway pressure ( **IPAP** ) and expiratory positive airway pressure ( **EPAP** ) are each set to predetermined prescription levels so that the bi-level pressure support device provides the prescribed **IPAP** and **EPAP** pressures at the appropriate phase of the breathing cycle. Bi-level pressure support...
- ...to the patient based on whether or not the patient is snoring is the Virtuoso' **CPAP** family of devices manufactured and distributed by Respironics, Inc. This auto-titration pressure support mode...

...could occur and adjusts the pressure output to avoid this result is the Tranquility® Auto CPAP device, also manufactured and distributed by Respironics, Inc. This auto-titration pressure support mode is ... pressure support device capable of operating in a PAV mode. Proportional positive airway pressure (PPAP) devices deliver breathing gas to the patient based on the flow generated by the patient. U.S. Patent...

...of operating in a PPAP mode.

Typically, the appropriate mode of pressure support, e.g., CPAP, bi-level, autotitration, PPAP, PAV, or a combination thereof is determined by the caregiver based...

...of the pressure support therapy. The operating parameters of the pressure support device, such as CPAP level, IPAP and EPAP levels in the case of a bi-level pressure support, percent of assistance...

...to the type of  
ided to the patient by the pressure support device, e.g., CPAP, pressure support treatment provided bi-level, auto-titration, PPAP, PAV, or a combination thereof. While...

...set up. For example, a typical bi-level pressure support system will operate as a CPAP device if the IPAP and EPAP levels are the same. Typically, once a patient is prescribed a mode of...

...that pressure support mode.

Those skilled in the art can also appreciate that a conventional ventilator system is typically capable of operating in different ventilation modes, with each mode representing a different technique for triggering and/or cycling the ventilator. It is common in a ventilator, for the caregiver to be able to select from a variety of modes of ventilation using selection devices provided on the ventilator. Because a ventilator is typically used in a hospital or other highly supervised environment, there is less chance...

...variables that can be altered or controlled in each operating mode. For example, in a CPAP device, the CPAP level is considered an operating parameter. In a bi-level device, the IPAP and EPAP levels are operating parameters. In the case of a PAV or PPAP device...for changing the mode or parameters using an authentication/authorization protocol, have access to the computer terminal on the device, or any combination thereof. As noted above, the pressure support device...

...the operating parameters of the pressure device have been set, the patient begins using the device to treat their breathing disorder and the operating mode and/or parameters remain in effect as long as the...

...example, it is not uncommon for an OSA sufferer to initially be treated with a CPAP device; and, thereafter, switched to a bi-level device in order to increase their comfort...

...requires that the patient receive an entirely new bi-level device in place of the CPAP device. This is obviously expensive and burdensome on the healthcare provider, who must deliver and install the new bi-level system in place of the existing CPAP device.

Alternatively, a bi-level device could be prescribed to the patient with the IPAP and EPAP levels set to the same pressure for the CPAP treatment, then changed to different levels for the bi-level treatment.

However, this approach is also not practical because, as noted below, changing even the IPAP and/or EPAP prescription levels requires that the authorized person have access to the device...

...process and cannot be done by the patient. For example, if the patient's initial CPAP or IPAP prescription pressure is too low, increasing the prescription pressure requires that the pressure support device...

...or healthcare provider.

Most conventional pressure support systems generate compliance data and store it in memory for downloading to an external computer via an RS232 port and/or for display on a display screen in the pressure... ability to receive, identify and organize the incoming data, which requires a relatively complicated, automated data processing capability.

#### SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to...

...the exterior surface of the housing is sized and configured for selectively receiving an information storage device, which is small, light weight, and easily transported, for example, in the mail. A terminal associated with the slot enables the information storage device to communicate with the controller via the terminal when the information storage device is in the slot. This configuration enables the controller to read information from the information storage device, write information to the information storage device, or both when the information storage device is in the slot. In this manner, the information storage device can, for example, provide data to the controller for establishing the operating parameters of the...

...terminal are replaced with a transceiver operatively coupled to the controller, so that the information storage device communicates with the controller via the transceiver when the information storage device is proximate to the transceiver, thereby avoiding the need to physically place the information storage device in contact with the pressure support device. The controller reads information from the information storage device, writes information to the information storage device, or both via the transceiver.

In a still further embodiment of the present invention, an...

...device is provided. The adapter, when provided in the slot in place of the information storage device, enables a variety of external devices, such as modem, a computer, or a communication device, to be operatively connected to the medical device, thereby enhancing the...

...of the pressure support system without adding dedicated communication links specific to each type of external device to be used.

It is yet another object of the present invention to provide an information storage device for use with a medical device, such as a pressure support system, to control its operation. In this embodiment of the present invention, the information storage device includes an identification storage area adapted to contain at least one of (a) information describing the information storage device itself, (b) information identifying a user to which the information storage device is assigned, and (c) information identifying a medical device assigned for use with the information storage device. The information storage device also includes an operating information storage area adapted to contain operating information for use...

...medical device.

It is yet another object of the present invention to provide an information storage device that receives and stores information from the medical device. In this embodiment of the present invention, the information storage device includes an identification storage area adapted to contain at least one of (a) information describing the information storage device itself, (b) information identifying a user to which the information storage device is assigned, and (c) information identifying a medical device assigned for use with the information storage device. The information storage device also includes a data storage area adapted to store data written thereon by the medical...

...regarding the use of the medical device, for example, can be stored on the information storage device. The information storage device is readily removeable from the medical device and can be provided to a monitoring center by simply mailing...

...a medical device having a slot defined in an exterior surface, (b) providing an information storage device that can be disposed in the slot, (c) inserting the information storage device into the slot, and (d) communicating information from the information storage device to the medical device or vice versa when the information storage device is in the slot. In this manner, the information storage device provides data to the controller for establishing the operating parameters

#### ...DRAWINGS

Fig. 1 is a schematic diagram of a pressure support system including an information storage device according to the principles of the present invention; Fig. 2 is a front perspective view of a pressure support device, information storage device, and a remote monitoring/programming center according to the principles of the present invention;

Fig. 3 is a schematic diagram illustrating one embodiment of the storage areas

in the information storage device of Figs. 1 and 2;

Fig. 4 is a schematic diagram illustrating various embodiments for the prescription data block in the information storage device of Fig. 3; Fig. 5 is a schematic diagram illustrating an alternative embodiment for the storage areas in the information storage device of the present invention; Fig. 6 is a schematic diagram of a further embodiment of...

...that generates a flow of breathing gas at an elevated pressure and an information storage device 34 that communicates with a controller 36 in pressure support device 32. As discussed in greater detail below, data, instructions, information, or commands from information storage device 34, in one embodiment of the present invention, are used to control the operation of the pressure support device. In addition, data or information from the pressure support device can be stored in the information storage device. Furthermore, the present invention contemplates that both of these functions can be performed so that information storage device 34 acts as a convenient and simple means for transferring information and/or instructions to or from the pressure support system. The details of information storage device 34 and its interaction with the pressure support device to achieve these functions are discussed...to the patient. For example, in a bi-level pressure support system, the change between IPAP to EPAP and EPAP to IPAP is triggered based on the changes in the patient's breathing cycle, which is detected...

...support system. Still other external sensors can include EMG electrodes provided on the patient, a **respiratory** belt that measures movement of the chest and/or abdomen, and a motion sensor to...

...for use in providing between the user and the pressure support device. In addition, a **computer** or printer terminal coupled to controller 36 can also constitute input/output device 60...

...controller 36, or both, can include a battery backup so that the operation of these **devices** or the information **stored** therein is not lost even if power to the pressure support device is interrupted.

As noted above, pressure support system 30 includes information **storage device** 34 that communicates with a controller 36. In an exemplary embodiment of the present invention, information **storage device** 34 is a so called "**smart card**" that contains a readable **memory**, a data storage area, or a combination of the two. Of course, information **storage device** 34 can also include an integrated circuit to provide the **smart card** with additional independent processing capabilities, such as performing diagnostic routines on the pressure support device, analyze the data provided to the information **storage device**, increasing the **processing** capability of **controller** 36, or any other function capable of being performed by a processor. In a preferred embodiment of the present invention, information **storage device** 34 is approximately the size, weight and shape of a conventional credit card so that...

...or from the patient via U.S. mail or other conventional postal-type carriers.

Information **storage device** 34 selectively inserts, as indicated by arrow A, into a slot 70 provided in housing...

...support device 32. A terminal 72 is provided within slot 70 so that the information **storage device** communicates with controller 36 when the information storage is properly disposed in the slot. As discussed below, controller 36 is capable of reading information from information **storage device** 34, writing information to the information **storage device**, or both. Terminal 72 is any conventional device capable of communicating with a **smart card**. As known to those skilled in the art, terminal 72 can include power couplings for providing power to the information **storage device**, where appropriate.

The present invention also contemplates that information **storage device** 34 is a conventional **computer** disc, such as a floppy disc, CDROM, or DVD **storage device**. In which case, terminal 72 includes the appropriate magnetic, electrical, or optical data accessing system for reading information from the disc, writing information to the **storage device**, or both.

One embodiment of the present invention contemplates that information **storage device** 34 provides the operating mode, operating parameters, or both for the pressure support system to controller 36. This embodiment enables the information **storage device** to be programmed at a remote location 74, such as at a pressure support monitoring...

...that can be provided by the patient's pressure support device, the patient's prescription **CPAP**, **IPAP**, **EPAP**, or maximum/minimum pressure can be stored on the information **storage device** at the remote location and mailed to the patient. The patient

merely inserts the information storage device into the slot in the pressure support system. Controller 36 reads the prescription pressure or ...

...breathing gas at the pressure level or within the pressure parameters specified on the information storage device. In a preferred embodiment of the present invention, the operating parameters read from the information storage device are stored in a memory (not shown) associated with controller 36 so that the information storage device can be removed and the pressure support device will continue to operate under the settings read from the information storage device, thereby eliminating the need for the information storage device once the pressure support device has been programmed.

It can be appreciated that this embodiment...

...purpose. Instead, the device provider or other caregiver merely sends the patient a new information storage device containing the new operating parameters. Alternatively, the patient can return the card to the device provider, who then reprograms the card at their operating center and returns it again to the patient. In either case, the burdens imposed on...

...the device provider has the ability to change the operating parameters stored on the information storage device, the security for the settings, i.e., operating parameters, of the pressure support device is ...

...pressure settings Fig. 3 is a detailed schematic diagram illustrating an exemplary embodiment of information storage device 34, and, in particular, the storage areas in the information storage device. Information storage device 34 in Fig. 3 is referred to as a "prescription card" because it contains information...

...pressure support device, and cannot receive data. In essence, it functions as a read-only memory card that sets the operating parameters of the pressure support device, which, in this embodiment...

...modifying, activating, or deactivating or otherwise controlling any other operating parameter using information or commands stored on information storage device 34.

In an exemplary embodiment of the present invention, information storage

device 34 includes the following three data storage areas: (1) a card identification block 76 that contains information describing the information storage device itself, (2) a user identification block 78 that contains information identifying a user to which information storage device 34 is assigned, and (3) a card prescription block 80 that contains contain prescription information...on their behalf. A card type block 84 contains information identifying the type of information storage device. As noted above, information storage device 34 is a "prescription card" in that it only contains information for setting the operating...

...pressure support device. The present invention, however, contemplates the existence of other types of information storage devices, such as a "data/prescription card" shown in Fig. 5 and described in detail below, ...

...to identify the specific format for the card identification block being

used in that information **storage device** . An address table block 88 in card identification block 76 defines the start and end...

...a unique card identification block that contains a card identification code unique to each information **storage device** , can be included in the card identification block.

This card identification code may be helpful in identifying and tracking the information **storage device** . In addition, the present invention does not necessarily require that each block 82-90 described...

...card identification block, so long as the card identification block contains information describing the information **storage device** to which the information **storage device** is assigned.

In the illustrated exemplary embodiment, user identification block 78 includes a user identification...

...to identify the specific format for the user identification block being used with that information **storage device** .

User identification block 78 also includes a user identification code block 94 and a user...

...94 contains at least one alphanumeric character that identifies a user to which the information **storage device** is assigned. For example, the user's social security number or a personal identification number (PIN) assigned by the card provider or the pressure support **device** provider may be **stored** in this block. User name block 96 contains information regarding a name of the user to which information **storage device** 34 is assigned. Preferably, the information contained in user identification code block 94, alone or...

...name information contained in user name block 96, uniquely identify a user to which information **storage device** is assigned.

The information contained in user identification block 78 can be used for security...

...a personalized greeting that is displayed on the input/output tenninal of the pressure support **device** when the information **storage device** is inserted into the slot in the pressure support device. This serves, for example, to notify the user that the information **storage device** has been correctly inserted into the slot and that he or she is using the correct information **storage device** . The present invention also contemplates that other information, such as information on the patient's medical condition, treatments, as well as advertisements can be stored on the information **storage device** and displayed to the user via input/output device 60. User identification block 78 includes...

...long as the user identification block contains information identifying the user to which the information **storage device** is assigned.

Card prescription block 80 includes a card prescription format block 102 that describes...to identify the specific format for the card prescription block being used in that information **storage device** .

Card prescription block 80 further includes an operating mode identification block 104 that identifies the...

...contain operating mode information identifying the mode of pressure



support to be provided as being CPAP , bi-level, auto-titration, PAV or PPAP, or a combination thereof. It should be noted...

...not be able to support certain modes of pressure support. For example, a relatively simple CPAP device is typically unable to provide bi-level, PPAP or PAV pressure support and cannot operate as an auto-titration pressure support system. If, for example, an information storage device in which operating mode identification block 104 specifies that the operating mode of pressure support is bi-level, is inserted into such a CPAP device, it may not be able to operate in this prescription mode. Therefore, an error...

...pressure support device or a bi-level device to be able to function as a CPAP device. The information contained in prescription identification block 104 would determine whether such a pressure support system would operate as a CPAP device or as a bi-level or an auto-titration device.

The present invention also...

...selected and altered, as needed, based on the operating mode information contained on the information storage device .

The present invention contemplates that when the information storage device is first produced, it is preferable that operating identification block 104 not specify any operating mode at all, so that the information storage device will only function as a prescription card after it has been appropriately programmed. For this...

...108 effectively locks or unlocks the ability to alter the pressure support system operating parameters stored in information storage device 34.

Ready for use block I 10 contains information for controlling whether the prescription information can be read from the information storage device . For example, if controller 36 in Fig. 1 sees a zero flag in this block...

...information contained in card prescription block 80. This feature of the present invention enables information storage device 34 to function as a one-time, read only prescription device, so that once the prescription information is read from the information storage device by the controller, this prescription information cannot be read again. This is accomplished by having...

...to change to a zero after the prescription information is initially read from the information storage device by the pressure support device. One purpose of this feature of the present invention is to prevent unrestricted use of the information storage device .

Rather than have the controller not read the prescription information contained in card prescription block...

...card prescription block 80 in the first place.

The present invention also contemplates that information storage device 34 can be configured such that the information contained in ready for use block I...a zero flag in ready for use block I 10. This enables a single information storage device to be used to set of the operating parameters of multiple pressure support devices. If...

...or more secondary residences or temporary sleeping quarters, the patient need only carry the information **storage device** with them and use it to set up the same operating parameters on each device...

...purposes.

Fig. 4 illustrates various embodiments for the prescription information block 112 in the information **storage device** of Fig. 3. More specifically, prescription information block I 12a illustrates the prescription information for a **CPAP** prescription, prescription information block 112b illustrates the prescription information for an auto-titration prescription, and...

...the operating parameters for the pressure support device.

Prescription information block 112a for a **CPAP** prescription includes a **CPAP** pressure block II 6, which contains information defining the prescribed **CPAP** pressure.

Prescription information block 112a for a **CPAP** prescription also includes a ramp shape block I 18 and a ramp time block...

...and ramp shape blocks in prescription information block 112a or at other locations in information **storage device** 34 for specifying the duration and shape of ramp cycles initiated after the initial ramp...

...same pressure support therapy session.

In the illustrated embodiment, prescription information block 112a for a **CPAP** prescription includes an auto on data block 122 and an auto off data block 124...block 124.

Prescription information block I 12c for a bi-level prescription includes an **IPAP** pressure block 130 and an **EPAP** pressure block 132. **IPAP** pressure block 130 includes information defining the prescribed **IPAP** pressure, and **EPAP** pressure block 132 includes information defining the prescribed **EPAP** pressure. As with prescription information block II 2a for a **CPAP** prescription, prescription information block I 12c for a bi-level prescription includes ramp shape block...

...off data block 124.

As discussed in U.S. Patent No. 5,551,418, the **IPAP**, **EPAP**, or both can be controlled in a ramp fashion, 'ust as with the **CPAP**. Ramp shape block I 18' contains

j  
information defining the shape for the change in the **IPAP**, **EPAP** or both during the ramp cycle. For example, the linear ramp selection in ramp shape block II 8' results in a linear increase in **IPAP** over the course of the ramp cycle with no change in the **EPAP**. The bi-level ramp selection results in a linear increase in both **IPAP** and **EPAP** during the ramp cycle. It can be appreciated that a great number of ramp shapes for **IPAP** and **EPAP** are possible, and information for selecting these ramp shapes can be provided in...

...operating parameters can be modified, controlled or set using the information contained in the information **storage device**.

For example, in a PAV or PPAP mode of pressure support, the degree or percentage...

- ...timed backup breath feature based on the information, instructions or commands contained in the information **storage device** . When enabled, the timed back-up breath feature causes the pressure support device, operating in...
- ...predetermined period of time. This is accomplished by providing a timer in the pressure support **device** . The **breathing** cycles of the patient are monitored in any conventional manner, and if the patient does...
- ...patient are examples of further operating parameters than can be input to the pressure support **device** via the information **storage device** . A still further embodiment of the present invention contemplates storing advertisements, a survey or questionnaire...
- ...or other information that may be relevant to the patient or caregiver on the information **storage device** . The advertisements, a survey or questionnaire, and/or other information are read from the information **storage device** and displayed on input/output device 60. If a question or a survey is provided...
- ...the answers to the survey and/or the scored results are stored on the information **storage device** for returning to the patient caregiver, either via the information **storage device** or via a communication link, such as the modem link discussed below. Presenting a questionnaire ...
- ...intended to require all of the abovedescribed operating parameters to be set by the information **storage device** . For example, there may be a situation where auto on or auto off is not...
- ...of the pressure support device can be set manually, i.e., without using the information **storage device** , or pre-set in advance, with the remaining parameters or operating mode being set by the data or commands contained on the information **storage device** .

Fig. 5 is a detailed schematic diagram illustrating another exemplary embodiment of an information **storage device** 34' for use in the pressure support system of the present invention. Information **storage device** 34' is similar to information **storage device** 34 of Fig. 3, except that information **storage device** 34' includes a data storage area 134.

Information **storage device** 34' in Fig. 5 is referred to as a "prescription/data card" because it contains...

- ...can also receive data, such as compliance data regarding the use of the pressure support **device** . Information **storage device** 34' includes the following data storage areas: (1) a card identification block 76' that contains information describing the information **storage device** itself, (2) a user identification block 78' that contains information identifying a user to which information **storage device** 34 is assigned, (3) a card prescription block 80 contains ...and (4) a card data control block 136.

In most respects, the features of information **storage device** 34' are identical to the those described above with respect to information **storage device** 34. For this reason, the common features of these two **storage devices** are not discussed below. However, the differences between these two types of information **storage devices** are

highlighted below.

Card identification block 76' includes a card type block 84' that contains information identifying the type of information **storage device**. As noted above, the type of information **storage device** 34' is a "prescription/data card", because it contains information for setting the operating parameters...

...138 that contains information identifying a pressure support system assigned for use with the information **storage device**. More specifically, pressure support device identification section 138 in the illustrated embodiment includes a unit...

...respectively, that together uniquely identifying a pressure support system assigned for use with the information **storage device**. This information can be used for security purposes to ensure that only the authorized prescription...

...containing information regarding the blocks of data stored in the data storage area.

Because information **storage device** 34' includes card prescription block 80, it can be used in the same manner as information **storage device** 34 to set the operating parameters of the pressure support system. However, the present invention contemplates omitting the card prescription block so that the information **storage device** cannot be used to set the operating parameters of the pressure support system, but can...

...support system, including information regarding the condition of the patient. In which case, the information **storage device** may be referred to as "data card", because its purpose is to store information provided...

...medical device. An example of "other information" that can be compiled by the information **storage device** includes data regarding the number of apneas experienced by the user the pressure support device...

...patient's pressure support therapy.

Because of its small size and ease of use, information **storage device** 34' can be easily and inexpensively mailed to a monitoring center. The monitoring center can...

...therapy, for example. Because the monitoring center controls the input of data from the information **storage devices** they receive, the **data processing** requirements for compiling this data is minimized. As noted above, this information may be of...

...s caregiver to assess the patient's wellbeing.

In the embodiments described above, the information **storage device** is described as a **smart card** or other data **storage medium** that inserts into a slot provided in the exterior of the pressure support device. The present invention, however, contemplates other techniques for communicating between the pressure support **device** and the information **storage device**. For example, Fig. 6 illustrates a pressure support system 30' in which a so-called "contact-less" information **storage device** 152 communicates with pressure support device 32'. The pressure support system shown in Fig. 6 is identical to that shown in Fig. 1, except that instead of inserting the information **storage device** into a slot to communicate with controller 36, an antenna or other transceiver

154 is provided in place of the slot to communicate between controller 36 and information storage device 152 without the need for the information storage device to physically contact the pressure support device. This embodiment of the present invention enables controller 36 and the information storage device to communicate with one another merely by placing the information storage device in the vicinity of the pressure support system. The present invention contemplates that transceiver 154 can be any conventional device for transmitting data, information or commands to the information storage device, receiving data, information or commands, from the information storage device, or both. For example, transceiver 154 can be an RF, infrared, sonic, ultrasonic, or optical transmitter.

The present invention also contemplates that the transceiver can transmit energy to information storage device for powering any components of the information storage device that may require power. For example, it is known to use an electro-magnetic field the present invention also contemplates providing a power source on the information storage device, such as a battery or solar cell, for powering the necessary components of the information storage device.

As noted above, the present invention contemplates providing slot 70 in the body or housing 66 of pressure support device 32 to enable the controller or processor 36 and the smart card information storage device 34 to communicate with one another via a terminal 72. The present invention contemplates utilizing...

...and terminal 72 for other purposes in addition to providing a docking port for information storage device 34. In particular, the present invention contemplates using slot 72 to communicate between an external device 160 and the components of pressure support device, such as controller 36. See Figs. 7...

...be provided in adapter 162. A communication link 172 selectively connects adapter 162 member to external device 160.

In the embodiment illustrated in Fig. 8, external device 160 is a modem 174 so that data, information, and/or instructions can be transmitted...

...part of the patient or caregiver, while still providing the flexibility to use an information storage device to control the pressure support device and/or monitor its operation.  
In a preferred embodiment...

...stored in modem 174, for example on a dedicated EEPROM device, as done in information storage device 34. This allows for a seamless transition between using the smart card information storage device 34 and modem 174 with adapter 162, because the operating parameters of the modem can be initialized, loaded, and modified in the same manner done with the smart card information storage device.

In the embodiment shown in Fig. 8, modem 174 includes a first output device 178...

...174 to provide additional information to the user.

While a modem is contemplated as one external device that can be coupled to controller 36 in pressure support device 32 via slot 70, it can be appreciated that other external devices 160 can be coupled to

controller 36 via slot 70. For example, a personal **computer**, palm or pocket **computer** or pocket organizer, printer, or any **computer** device can be coupled to the controller in pressure support device 32 by providing an...

...diagnostic routines on the pressure support device. Perhaps more importantly, the need for a dedicated **computer** terminal, such as an RS-232 port is eliminated in favor of a multi-function port that can support both a **smart card** and an adapter.

A further embodiment of the present invention contemplates using adapter 162 to...70 in pressure support device 32, which normally only holds the credit card sized information **storage device**. As a result, it is necessary to ensure that the hardware remains engaged within slot...

...182, shown in Figs. 7 and 9, for maintaining a positive engagement between the information **storage device** and slot 70. In an exemplary embodiment of the present invention, retaining member 182 is...

...second members 188 adapted to receive internal interface portion 166 of adapter 162 or information **storage device** 34. Flexible arms 190 are provided on opposing sides of slot 184. The end of...

...a notch (not shown) provided on each side of internal interface portion 166 or information **storage device** 34, thereby increasing the resistance to pull out of the internal interface portion 166 or information **storage device** 34 from slot 70.

In the embodiments discussed above, the information **storage device** is described for use in conjunction with a pressure support system. It is to be understood, however, that the present invention further contemplates using the information **storage device** as a means to communicate with and/or control the operation of other medical **devices**. For example, information **storage device** can be provided in a glucose monitor so that each time the patient checks his or her blood sugar level, the results are stored on the information **storage device**, which can then be sent to the caregiver for review or analysis. Other medical devices in which the above-described information **storage device** technique for communication can be used include: light therapy devices, magnetic therapy devices, pulse oximeters...

#### Claim

... of the housing, wherein the slot is sized and configured for selectively receiving an information **storage device**, and a terminal (72) associated with the slot such that an information **storage device** communicates with the controller via the terminal responsive to the information **storage device** being disposed in the slot, wherein the controller is adapted to at least one of (1) read information from the information **storage device** and (2) write information to the information **storage device** via the terminal.

2 The pressure support system of claim 1, further comprising at least...

...coupled to the controller for monitoring usage of the pressure support system.

6 An information **storage device** (34) adapted for use with a medical **device**, the information **storage device** comprising:  
an identification **storage area** (76, 78) adapted to contain at least one of (1) information describing the information **storage device** itself,  
(2) information identifying a user to which the information **storage**

device is assigned, and (3) information identifying a medical device assigned for use with the information storage device ; and a first information storage area (80) adapted to contain operating information for use in controlling an operation of such a medical device .

7 The information storage device of claim 6, wherein the identification storage area includes both 1) an information storage device identification area (76) adapted to contain information describing the information storage device itself and 2) a user identification area (78) adapted to contain information identifying a user to which the information storage device is assigned.

8 The information storage device of claim 7, wherein the identification area further includes a medical device identification area adapted to contain information uniquely identifying a medical device assigned for use with the information storage device .

9 The information storage device of claim 8, further comprising a data storage area adapted to store data written thereon by such a medical device .

10 The information storage device of claim 6, further comprising a data storage area adapted to store data written thereon by such a medical device. 11. The information storage device of claim 6, wherein the first information storage area includes:  
a patient name area adapted to contain information regarding a name of a user  
to which the information storage device is assigned; and  
a patient identification area adapted to contain at least one alphanumeric character identifying a user to which the information storage device is assigned.

12 The information storage device of claim 6, further comprising a first control data storage area adapted to contain information that controls whether the operating information can be read from the information storage device .

13 The information storage device of claim 6, further comprising a second control data storage area adapted to contain information that controls whether the operating information can be erased from the information storage device .

14 The information storage device of claim 6, further comprising a display data storage area adapted to contain information to be displayed on such a medical device .

15 The information storage device of claim 6, wherein the medical device is a pressure support device, and wherein the...

...pressure support device and operating parameter information designating an operating parameter of the pressure support device .

16 An information storage device adapted for use with a medical device , the

information storage device comprising:  
an identification storage area adapted to contain at least one of (1) information describing the information storage device itself, (2) information identifying a user to which the information storage device is assigned, and (3) information identifying a medical system assigned for use with the information storage device ; and  
a data storage area adapted to store data written thereon by such a medical device .

17 The information storage device of claim 16, wherein the identification storage area includes both a storage device identification area adapted to contain information describing the information storage device itself and a user identification area adapted to contain information identifying a user to which the information storage device is assigned.

. The information storage device of claim 17, wherein the identification area further includes a medical device identification area adapted to contain information uniquely identifying a medical device assigned for use with the information storage device .

19 A pressure support system (30, 30') comprising:  
a pressure support device (32, 32') comprising...

...surface of the housing, and  
a terminal (72) associated with the slot; and  
an information storage device (34) adapted to be selectively disposed in the slot, the information storage device comprising:  
an identification storage area (76, 78) adapted to contain information identifying at least one of (1) information describing the information storage device itself, (2) information identifying a user to which the information storage device is assigned, and (3) information identifying the pressure support device assigned for use with the information storage device , and  
at least one of (a) a first information storage area (80) adapted to contain...

...data written thereon by the pressure support device,  
wherein the controller communicates with the information storage device via the terminal responsive to the information storage device being disposed in the slot, and wherein the controller is adapted to at least one of (1) read information from the information storage device and (2) write information to the information storage device via the terminal.

20 The pressure support system of claim 19, further comprising an adapter ...

...disposed in the slot, wherein the adapter provides communication access between the controller and an external device responsive to being inserted into the slot.

21 The pressure support system of claim 19...

...a medical device having a slot defined in an exterior surface thereof; providing an information storage device sized and configured to be selectively disposed in the slot;  
inserting the information storage device into the slot; and



communicating information from the information storage device to the medical device responsive to the information storage device being disposed in the slot.

24 The method of claim 23, further comprising causing the medical device to operate in a predetermined manner based on information read from the information storage device responsive to the information storage device being inserted into the slot.

25 The method of claim 24, further comprising preventing such a medical device from receiving the information from the information storage device after the information has been initially provided to such a medical device.

26 The method:

...comprising:

monitoring usage of the medical device; and  
writing information regarding usage of the medical device onto the information storage device.

The method of claim 23, further comprising prompting a user to remove the information storage device responsive to an occurrence of a predetermined condition.

28 The method of claim 27, wherein the predetermined condition includes: a failure of the medical device to communicate with the information storage device,

an elapse of a predetermined amount of time since the information storage device was disposed in the slot in the pressure support device, and

an accumulation of data in the information storage device exceeding a predetermined threshold.

29 The method of claim 23, further comprising writing information from the pressure support device to the information storage device.

30 The method of claim 29, further comprising:

removing the information storage device from the slot in medical device;

transporting the information storage device to a remote location; and

downloading information concerning the pressure support device from the information storage device at the remote location. 31. A method of reporting information from a medical device...

...e support device having a slot defined in an exterior surface thereof;

providing an information storage device sized and configured to be selectively disposed into the slot;

inserting the information storage device into the slot; and

communicating information to the information storage device from the medical device responsive to the information storage device being disposed in the slot.

32 The method of claim 31, further comprising:

removing the information storage device from the slot in medical device;

transporting the information storage device to a monitoring center; and

downloading information concerning the pressure support device from the

information storage device at the monitoring center.

33 The method of claim 31, further comprising:  
monitoring usage of the medical device; and  
writing information regarding usage of the medical device onto the  
information storage device.

34 The method of claim 31, further comprising prompting a user to  
remove the information storage device responsive to an occurrence of  
a predeten-nined condition.

35 The method of claim 34...

...the predetermined condition includes:  
a failure of the medical device to communicate with the information  
storage  
device ,  
an elapse of a predeten-nined amount of time since the information  
storage  
device was disposed in the slot in the medical device, and  
an accumulation of data in the infon-nation storage device exceeding  
a  
predetermined threshold.

36 A pressure support system (30, 30') comprising:  
pressure generating means...predetermined  
condition includes:  
a failure of the pressure support device to communicate with the  
information  
storage device ,  
an elapse of a predetermined amount of time since the information  
storage  
device was disposed in the slot in the pressure support device, and  
an accumulation of data in the information storage device exceeding a  
predetermined threshold.

39 The pressure support system of claim 36, further comprising monitoring  
...  
...further comprising means for  
preventing the controlling means from receiving operating information  
from the information storage device after such operating information  
has been initially provided to the pressure support device.

42 The...

...within the receiving means, for providing a communication link between  
the controlling means and an external device responsive to being  
disposed on the receiving means.

. A pressure support system (30, 30') comprising...

...pressure generating system;  
a transceiver (154) operatively coupled to the controller such that an  
information storage device (152) communicates with the controller via  
the transceiver responsive to the information storage device being  
disposed proximate to the transceiver, wherein the controller is adapted  
to at least one of (1) read information from the information storage  
device and (2) write information to the information storage device  
via the transceiver.

44 A method of configuring and pressure support system, comprising:

providing a pressure support system having a slot defined in an exterior surface thereof;  
providing an information **storage device** sized and configured to be selectively disposed in the slot;  
inserting the information **storage device** into the slot;  
communicating first information from the information **storage device** to the medical device responsive to the information **storage device** being disposed in the slot; and configuring the pressure support system based on the first...

...further comprising preventing the pressure support system from receiving the first information from the information **storage device** after the first information has been initially provided to such a medical device.

47 The...

...support system; and  
writing information regarding usage of the pressure support system onto the information **storage device** .

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00751330 \*\*Image available\*\*

**METHOD AND APPARATUS FOR OBTAINING PATIENT RESPIRATORY DATA**  
**PROCEDE ET APPAREIL D'OBTENTION DE DONNEES RESPIRATOIRES D'UN PATIENT**

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**METHOD AND APPARATUS FOR OBTAINING PATIENT RESPIRATORY DATA**

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Detailed Description

Claims

English Abstract

A system for collecting patient **respiratory** information includes a base unit (12), and a **removable** mouthpiece unit (14). The mouthpiece unit (14) includes sensors that sense parameters of a patient's breath...  
...in chronological fashion for later analysis by a physician. The mouthpiece unit (14) includes a **memory** for storing identification information for a patient who has been assigned the mouthpiece unit (14)  
...

Detailed Description

**METHOD AND APPARATUS FOR OBTAINING**

**PATIENT RESPIRATORY DATA**

**FIELD OF THE INVENTION**

The invention relates generally to medical devices and, more specifically, to devices for measuring and logging patient **respiratory** information.

## BACKGROUND OF THE INVENTION

**Respiratory** problems are relatively common in society today. For example, some I O estimate that nearly 5% of the population of the United States suffer from asthma.

Effective treatment of **respiratory** conditions can be complicated, sometimes requiring continuous monitoring and recording of respiratory function and symptoms in...

...threatening attacks or the like.

As can be appreciated, the procedures for monitoring and recording **respiratory** function and the use of medicines can be complicated and time consuming. Much of the responsibility for maintaining accurate records of **respiratory** function and administration of medication falls upon the patient, who must then report recorded information...

...need exists for a method and apparatus for accurately collecting information about a patient's **respiratory** condition from the patient. The method and apparatus will preferably be simple and straightforward to ...

...present invention relates to a system that is capable of accurately collecting and recording patient **respiratory** information for use, for example, in developing/modifying a treatment regimen for the patient. The system includes both measurement functionality for measuring the patient's present **respiratory** condition and storage functionality for storing and organizing the measured information. In addition, the system...

...patient management functionality can prompt the patient when it is time to take an appropriate **respiratory** reading and also coach the patient during the reading to increase the likelihood of proper...

...conjunction with input/actions by the patient. In addition, the system includes at least one **detachable** mouthpiece **unit** for insertion into the base unit when a measurement is to be performed. The mouthpiece unit includes the sensors that are required for sensing **respiratory** function related parameters from a patient's breath when the patient blows, or possibly inhales...

...with any relevant treatment suggestions.

In accordance with one aspect of the present invention, each **detachable** mouthpiece **unit** includes an internal **memory** for storing, among other things, identification information identifying a patient having exclusive use of that...

...unit is transferred to the base unit which stores the identification information in its internal **memory**. Results of all subsequent tests performed by the base unit using that inserted mouthpiece unit are...

...unit, can make use of a single base unit without confusion I O as to which **respiratory** -related information corresponds to which patient. In addition, because each patient uses an entirely different...one embodiment of the present invention. As illustrated, the system 10 includes: a portable base **unit** 12, a **detachable** mouthpiece **unit** or device 14 which can be removably coupled to the portable base unit 12, a ...

- ...unit 12 includes the measurement and storage functionality that is used to collect and record **respiratory** related information for the patient. The mouthpiece unit 14 plugs into the base unit 12...
  - ...base unit 12 can be carried by a patient for use in collecting and storing **respiratory** -related information about the patient as the patient goes about his ordinary daily routine. Alternatively...
  - ...a multiple patient environment, such as a hospital or a home having two or more **respiratory** patients, to collect data from a number of different patients. As will be described in...
  - ...patient (e.g., whether the patient inhaled the medication too fast, etc.). As with the **respiratory** measurement information, this information is also stored within the base unit 12 for future use...
  - ...in the base unit 12 for the identified patient and stores it within an internal **memory**. The stored data is then transferred to the physician data collection station 18 via communication path 20 at an appropriate time.
- After the **respiratory** -related data has been transferred to the docking station 16, it does not have to...
- ...data collection station 18 is a device used by a physician to retrieve and organize **respiratory** information about his patients. Typically, the physician data collection station 18 will be a **desk top** personal **computer** used by the physician to perform and organize his daily practice. After a patient's **respiratory** -related information has been transferred to the physician data collection station 18, the physician analyzes...
  - ...docking station 16, via the communication path 20, where it is stored in the internal **memory** of the docking station 16. If the corresponding base unit 12 is still docked within...
  - ...by the patient. Otherwise, the docking station 16 will hold the information in its internal **memory** until the appropriate base unit 12 is re-inserted. Alternatively, the physician can call the...
  - ...device can be used within the base unit 12, including, for example, a general purpose **microprocessor**, a digital signal processor, a reduced instruction set **computer**, or a complex instruction set **computer**. Because the portable base unit 12 is battery powered, processors capable of low power operation...
  - ...12 includes: a measurement unit 38, a patient performance manager (PPM) 40, a performance event **memory** 42, a wireless transceiver 44 coupled to a transducer 45, a voice synthesis unit 46...
  - ...the LCD display 50 or the speaker 54 when it is time to take a **respiratory** reading. Likewise, the PPM 40 can query the patient with respect to any symptoms the...
  - ...time.

The PPM 40 then records the patient's activities/responses in the performance event **memory** 42 in a chronological fashion. In one embodiment, all entries stored in the performance event **memory** 42 are time tagged with both date and time-of-day so that an accurate time

record is maintained of the patient's activities.

When a **respiratory** measurement is to be performed, the PPM 40 first checks to determine whether a **detachable** mouthpiece unit 14 is currently installed. If not, the patient is prompted using the speaker 54 and...

...installed, it enables the measurement unit 38 to receive and process raw data from the **detachable** mouthpiece unit 14. The PPM 40 then prompts the patient to blow into the mouthpiece unit 14...

...unit 38, the PPM 40 stores the results of the processing in the performance event **memory** 42 as described above. The PPM 40 can also display the results of the processing...

...one aspect of the present invention, the mouthpiece unit 14 includes an internal **memory** for storing, among other things, identification information identifying a patient associated with the mouthpiece unit...

...the results of all measurements made using that mouthpiece unit 14 in the performance event **memory** 42 in association ...the portable base unit 12 from bed to bed in a hospital ward to collect **respiratory** data from a number of different patients each having his/her own mouthpiece unit 14...

...recorded in the hospital's records, each patient's data can be delivered to the **computer** of his/her personal physician.

In accordance with one embodiment of the present invention, the base unit ...

...of the patient are recorded by the PPM 3040 in the performance event **memory** 42 along with corresponding time information.

As described above, the PPM 40 is also capable of querying the patient as to symptoms that are relevant to his **respiratory** condition. The patient's responses are then time tagged and stored within the performance event **memory** 42 for later analysis by the physician. For example, the PPM 40 can ask the...

...for example, at predetermined times of day, before and after medication use, or after a **respiratory** measurement has been made. In addition, the patient can input symptom information at any time...

...base unit 12 and information contained within the signal is recorded within the performance event **memory** 42 with an appropriate time stamp. The wireless transceiver 44 then transmits an acknowledgment signal... back to Fig. 3, the electronics portion 66 of the circuit board 62 includes a **memory** I/O for use in storing information about the corresponding mouthpiece unit 14. The **memory** I/O is preferably a non-volatile semiconductor **memory** (e.g., an EEPROM) that will not lose its contents during periods when little or no power is being I/O supplied to the **memory** I/O (such as when the mouthpiece unit 14 is detached from the base unit 12). In a preferred embodiment, the **memory** I/O is used to store patient identification information identifying a patient having exclusive use...

...the corresponding mouthpiece unit 14. The patient identification information will normally be stored in the **memory** I/O by the physician when he assigns the corresponding mouthpiece unit 14 to 5...

...64 of the corresponding circuit board 62.

The calibration data can be stored in the **memory** I 10 during manufacture and could be changed periodically as a result of re-calibrations.

The **memory** 1 1 0 is operatively connected to pins within the connector 68 to provide access...

...embodiment of the invention, the PPM 40 knows where particular information is stored within the **memory** I 1 0 and retrieves this information when the mouthpiece unit 14 is initially inserted...

...removed. The PPM 40, as discussed previously, uses the patient identification information retrieved from the **memory** I 1 0 to index the patient performance information stored in the performance event **memory** 42.

In situations where multiple patients are sharing a single base unit 12, this indexed...

...a patient currently using the base unit 12.

The sensor calibration information stored within the **memory** 1 1 0 will be retrieved by the measurement unit 3 8 when the mouthpiece...

...received from the sensors into meaningful measurement data.

In one embodiment of the invention, the **memory** 1 1 0 also stores **respiratory** performance information related to the corresponding patient. For example, the patient's personal best PEFR score can be stored in the **memory** I 1 0 for later comparison. The 1 5 PPM 40 can read this score from the **memory** II 0 and compare it to a current PEFR reading for the patient. If the...

...the personal best, the patient is congratulated and the previous personal best score within the **memory** 1 1 0 is replaced by the current score. If the current score is lower, the patient is informed of how much lower it is. The **memory** II 0 can also include information identifying the patient's physician (e.g., physician's...

...be used by the docking station 16, for example, to transfer a particular patient's **respiratory** -related information to the appropriate physician data collection station 18 (see Fig. 1).

With reference...

...the base unit 12. The cable assembly 1 16 allows a patient to perform a **respiratory** test from a position that is somewhat removed from the base unit 12. This additional...such as, for example, PEFR and FEVI levels. In one embodiment, a display of the **respiratory** maneuver can be provided. After these are displayed for a predetermined period of time, other indications...mouthpiece unit 14 and store all subsequent test results corresponding to that patient within a **memory** inside the base unit 142, along with date and time information.

In a hospital environment...

...patient the results of the test. The data is subsequently transferred to an attending physician's **computer** 148 via, for example, hospital network 150 for use in 1 5 treating/monitoring the...



...he is in the hospital. The data can also be stored in the hospital's **computer** files on network 150 to maintain appropriate records for the patient. The stationary base unit...

...other information) already stored in the mouthpiece unit 14 to automatically and chronologically record all **respiratory** measurement results for the patient while he is in the hospital. In addition, the stationary...

...mouthpiece units 14, the hospital need not provide and program new mouthpieces for every new **respiratory** patient admitted to the hospital, resulting in significant cost savings for the hospital and the patient. Storage of physician identification information within the **memory** II 0 of the mouthpiece unit 14, as discussed previously, is especially advantageous in a...

...use physician identification information stored within a patient's mouthpiece unit 14 to transfer all **respiratory** -related data collected from the patient while in the hospital directly to the **computer** of the patient's personal physician (via, for example, the PSTN 152 or other public...

#### Claim

I . A method for obtaining information related to **respiratory** functions from a number of patients, comprising:  
 providing a base unit;  
 providing a first mouthpiece...

...processor and said first patient information includes first patient data related to at least one **respiratory** function of said first patient and said step of obtaining said first patient information includes...

...as claimed in Claim 4, wherein:  
 3 0 said base unit includes a base unit **memory** and said first mouthpiece assembly includes a first mouthpiece **memory** and said step of obtaining said first patient information includes storing said first patient data correlated with said first patient identification information in said base unit **memory** .

6 A method, as claimed in Claim 5, wherein:  
 said step of obtaining said second patient information includes storing second patient data correlated with said second patient identification information in **memory** locations of said base unit **memory** previously having said first patient data correlated with said first patient identification information.

7 A...

...information and 1 5 then downloading said first patient identification information to a first mouthpiece **memory** of said first mouthpiece assembly using said docking station.

9 . A method, as claimed in...

...by the first patient, information related to a first patient symptom into a base unit **memory** of said base unit.

11 A method, as claimed in Claim 10, wherein:

said entering...

...base unit.

14 A system for obtaining information from a number of patients related to

**respiratory** functions, comprising:

a base unit including a processor and a base unit **memory** for storing patient information;

a first mouthpiece assembly that can be connected to said base unit and including a first mouthpiece **memory** that stores first patient identification information; and

a second mouthpiece assembly that can be connected to said base unit and including a second mouthpiece **memory** that stores second patient identification

information;

wherein said processor is used to obtain said first patient identification information when said first mouthpiece **memory** is connected to said base unit and said processor is used to obtain said second patient identification information from said second mouthpiece **memory** when said second mouthpiece assembly is connected to said base unit.

15 A system, as **memory**.

19 A system, as claimed in Claim 14, further including:

a cable assembly for use...

...said first mouthpiece assembly during a test.

20 A system for obtaining information related to **respiratory** functions from

at least one patient, comprising:

a mouthpiece assembly that includes a mouthpiece device...

...which the patient exhales, a flow board connected to said mouthpiece device, and a mouthpiece **memory** associated with said flow board that stores identification information for a first patient; a base...

...assembly and including a processor for reading said first patient identification information from said mouthpiece **memory** and a base unit **memory** for storing said first patient identification information with **respiratory** -related data from the first patient, with said processor correlating said patient data with said...

...as claimed in Claim 20, further including:

a second mouthpiece assembly that includes a mouthpiece **memory** for storing identification information for a second patient different from the first patient and in...

...second mouthpiece assembly is joined to said base unit after said first mouthpiece assembly is **removed** therefrom.

22 A **system**, as claimed in Claim 20, further including. a docking station in communication with said mouthpiece assembly for use in downloading said first patient identification information to said mouthpiece **memory**.

23 A system, as claimed in Claim 20, wherein:

said base unit includes a display...

...I 0 said base unit includes means for controlling a storing in said base unit **memory** of first patient data related to exhalation by the first patient using said mouthpiece assembly...

...distal  
connectors.

27 A system for obtaining information from at least one patient related to

**respiratory** functions, comprising:  
a mouthpiece assembly including a mouthpiece device into which a patient exhales; a...

...operatively connected to said mouthpiece assembly and including a processor for processing patient data, a **memory** for storing patient data, and a display for displaying at least patient instructions; and  
a...

...28 A system, as claimed in Claim 27, wherein:  
said mouthpiece assembly includes a mouthpiece **memory** for storing patient identification information.

29 A system, as claimed in Claim 27, wherein:  
said...

...LCD DISPLAY 50  
WIRELESS 40  
52  
TRANSCEIVER KEYPAD  
PATIENT  
PERFORMANCE  
MANAGER  
PERFORMANCE SPEAKER 54  
EVENT **MEMORY**  
48  
56:  
f CROPHONE  
VOICE VOICE  
SYNTHESIS RECOGNITION

.....  
FIGO 2  
/10  
64  
70  
60 66...CUSTOM SYMPTOM =4 BEST  
PATIENT GUESS PRESS E TO EDIT" 0-999  
FOR BLOW VIA PC AORV  
"PRESS E "10/3010:33:12 CE  
RESULTS" DYSPNEA = 5"  
:A OR V  
"11...

32/3,K/172 (Item 172 from file: 349)  
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00515848 \*\*Image available\*\*

VENTILATOR CONTROL SYSTEM AND METHOD  
SYSTEME ET PROCEDE DE COMMANDE D'UN VENTILATEUR

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VENTILATOR CONTROL SYSTEM AND METHOD

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Detailed Description

Claims

English Abstract

...exhalation assist device for adjusting the airway resistance in an exhalation circuit of a medical ventilator (17). The device includes a set of pressure, airflow and airway sensors (7, 11, 9), a controlling processor, a user interface (24, 26), and a ventilatory unit in communication with a medical ventilator (17). Data relating to pressure within the ventilatory unit and data relating to exhalation airflow, exhalation circuit pressure and exhalation circuit resistance are...

...signal that will change the applied negative pressure applied to the exhalation circuit by the ventilatory unit. The amount of negative pressure applied during the breathing cycle is varied by the...

...the patient airway (21) remains constant at a level greater than zero and less than PEEP.

French Abstract

...un niveau superieur a zero et inferieur a la pression positive en fin d'expiration ( PEEP ).

Detailed Description

Ventilator Control System and Method

Field of the Invention

The invention relates generally to the field of respiratory assist devices such as ventilators. In particular, the invention relates to a ventilator control system and method for controlling a ventilator pneumatic system.

Background of the Invention

A medical ventilator delivers gas to a patient's respiratory tract

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(GILMORE, ET AL)

and is often required when the patient is unable to maintain adequate **ventilation**. **Mechanical ventilation** is the single most important therapeutic modality in the care of critically ill patients. Known **ventilators** typically include a pneumatic system that delivers and extracts gas pressure, flow and volume characteristics...

...as the condition of the patient changes. Such adjustments, although highly desirable, are difficult to **implement** with known **ventilators** because the control system demands continuous 15 attention and interaction from the clinician.

Further, patients requiring **ventilatory** assistance must overcome airway resistance in the breathing circuit during exhalation. This resistance, combined with...

...breathin without compromising patient ventilation requirements.

Summm of the Invention

The invention relates to a **ventilatory** assist **device** that decreases the resistance to exhalation in the exhalation circuit of a medical **ventilator**. The **device** adjusts the resistance within the exhalation circuit by generating a negative pressure around a gas...

...relating to airway pressure, airway resistance or applied negative pressure through a control panel. A **microprocessor** within the **data processing unit** of the device compares these values with data for airway pressure, airway resistance and applied negative pressure that have been measured or calculated by sensors within the device. The **microprocessor** then adjusts the amount of negative pressure to be created within the gas exchange l...

...regulates the flow through the Venturi valve in response to signals it receives from the **microprocessor** within the **data processing unit** that calculates the amount by which the applied negative pressure is to be changed. A pressure sensor in communication with the **ventilatory** unit measures the negative pressure applied to the gas exchange reservoir and transmits these data to the **data processing unit**.

A method of exhalation assist compensates for resistance to gas flow encountered by a patient...

...circuit so as to alter the measured values to reach the desired values.

The term "**ventilator** control setting structure" is defined as a collection of information sufficient to control one parameter...

...The term Cccycle control structure" is defined as a collection of waveforin samples and a **ventilator** control setting Structure for each parameter. The term "phase control structure" is defined as a collection of phase switching rules that defines how the **ventilator** control settings are to be utilized and a **ventilator** control setting for each controllable parameter that exists in the **ventilator**. Each phase has one or more triggers that are tested every cycle (4 Msecs per cycle) to decide which **ventilator** control setting to use.

I 0

The term "breath control structure" is defined as a collection of phase switching rules that defines how and when one **ventilatory** breath phase is to switch to another **ventilatory** breath phase and a phase control structure for each phase of breath defined by the specified breath.

Breath phases break up a **ventilatory** breath into as many phases as desired in order to control 1 5 inspiration, pause, expiration assist and **PEEP** with any desired level of control for the specified breath. Each breath has one or...

...is defined as a collection of breath switching rules that defines how and when one **ventilatory** breath is to switch to another **ventilatory** breath and a breath control structure for each type of breath defined by the specified...in the accompanying drawings.

FIG. 1 is a block diagram of an embodiment of a **ventilator** of the invention.

FIG. 2 is a detailed block diagram of a display controller.  
FIG...

...block diagram of an embedded controller.

FIG. 4 is a detailed block diagram of a **ventilator** pneumatic unit.

FIG. 5 is a diagram illustrating an embodiment of the adjustment of negative...

...determine patient ventilation triggering.

FIG. 7 is an illustration of a display screen when the **ventilator** control system is in the operational mode.

FIG. 8 is an illustration of a section...

...FIG. 10 is a flow chart of the data structure hierarchy employed by the **ventilator** control system.

FIG. 12 is an embodiment of a flow chart of an exhalation assist...

...the invention.

FIG. 13 is an illustration of a simulation mode display screen for the **ventilator** control system.

FIG. 14 is a functional block diagram of the simulator portion of the **ventilator** control system

FIG. 15 is an illustration of a section of the display screening showing a waveform shaper.

FIG. 16 is an illustration of a therapy programming screen for the **ventilator** control system.

#### Detailed Descriptio

1. **Ventilator** Control System - The invention features a **ventilator** control system for controlling a **ventilator** pneumatic system in a medical **ventilator**. The **ventilator** control system provides a clinician with complete control of a patient's airway flow and pressure throughout the **respiratory** cycle, and thereby enables the clinician to determine the optimal therapy for the patient. In...

...this situation, negative pressure can be applied to the exhalation circuit of the patient's **ventilator** to reduce the resistance to airflow.

I 0 Because resistance to airflow is an exponential...be averted.

If airway pressure rises above the clinically indicated level of positive endexpiratory pressure ( **PEEP** ), the lung will be overpressurized thus the effective airway pressure throughout the expiratory cycle is filtrated throughout the expiratory phase under precise algorithmic control. The clinical benefit of a certain **PEEP** level will be diminished.

Thus, the effective airway pressure throughout the expiratory cycle must remain greater than zero and less than **PEEP** .

FIG. I is a block diagram of a **ventilator** including a **ventilator** control system I0 incorporating the features of the invention. The **ventilator** control system I0 includes a display controller 12 and an embedded controller 14. The display...

...interface to the clinician 16, and the embedded controller 14 provides an interface with a **ventilator** 17 providing ventilation to a patient 20. The display controller 12 and the embedded controller 14 each include **memory** (not shown) and are electrically coupled via a shared **memory** interface 15. Data from the display controller 12 and the embedded controller 14 are stored...

...embedded controller 14 to calculate the amount of negative pressure to be generated in the **ventilator** 17 in order to produce an airway pressure greater than zero and less than positive...

...gas delivered from the source of pressurized gas 45 through a Venturi valve within the **ventilator** 17 to produce this negative pressure. One I 0 embodiment of such a pneumatic system...

...by reference. A pressure sensor 51 measures the amount of negative pressure produced within the **ventilator** 17 and transmits these data to the embedded controller 14. These data are stored in...

...controller 12. Each of these target values is compared with a corresponding current value of **ventilatory** unit pressure, airway pressure, airway flow and air-way resistance by the embedded controller 14 changes the amount of negative pressure produced by the **ventilator** 17. The **ventilator** 17 is in pneumatic communication with a flexible tubing 21 capable of attachment to a...

...application, serial number 08/352,658, incorporated herein by reference.

The safe performance of the **ventilator** I 0 is enhanced by the redundancy of the two independent display controller 22 and embedded controller 30 processors, which continually check each other's performance via the shared **memory** interface 15. The embedded controller 14 communicates its status, and that of the patient, to...

...the last known good settings if communication becomes lost. The two systems which comprise the **ventilator** control system I0 give both audible and visual messages when an alarm condition exists, and...

...absence of breathing). During operation, both systems perform background tests to detect system faults. The **ventilator** provides a series of reduced operation modes to provide life support if system capability is ...highly flexible means to change control settings.

The display controller 12 is a powerful graphics **workstation** with hardware and I 0 software components. In one embodiment, the clinician

interacts with the...

...to the monitor. In one embodiment, the processor 22 is included in a single board **computer** which also includes **RAM**, an integrated high speed graphics 15 driver, and an integrated dual port **memory**. The display controller 12 also includes a hard disk drive 23.

While the display controller 12 provides interpretation and decision support information on the display 24, the **ventilator** 17 does not change any breath control parameters unless directed by the clinician 16. Nevertheless, the display controller 12 provides a flexible **user interface** with multiple interactive levels, from simple text menus of controls for inexperienced users, to complete...

...embedded controller 14 includes a system board 28, a real time data processor 30, a **ventilator** processor 32 and an air-way processor 31. The real time processor 30 manages sensor data collection from the sensor monitoring system 19, processes measured data, performs alarm/fault detection and provides control data to the **ventilator** 17. The embedded controller 14 further receives data input by the clinician 16 and accesses...

...system 19 relating to airway pressure, flow and resistance. A second data processor 32, a **ventilatory** unit processor, receives signals from the pressure sensor 51 in communication with the **ventilatory** pneumatic system 18. Signals from both data processors 31 and 32 are transmitted to a...to airway pressure, flow and resistance to preselected values and then calculating the change in **ventilatory** unit negative pressure required to affect the desired change in airway resistance.

In more detail, and referring also to FIG. 4, a block diagram of the **ventilator** 17 in communication with the flexible airway 21 that is the conduit for inhalation from...

...airway 21 to assist the patient's exhalation through the canister 49 into the medical **ventilator** 7.

Pressure within the flexible canister 49 is measured by a pressure sensor 51...

...controller 14.

Now referring also to FIG. 5 a detailed functional block diagram of the **ventilator** control system 10 is depicted. As shown, the clinician 16 manipulates a control setting slider...

...the clinician's inputs and creating 40 a breath control structure which is stored in **memory**. The display I/O controller 12 transmits the breath control structure to the embedded controller...

...panel 36. The embedded controller 14 initially stores 44 the breath control structure in local **memory**.

The embedded controller 14 re-validates 46 the settings within the breath control structure.

The embedded controller 14 **implements** 48 the validated **breath** control structure 48 using a breath control algorithm 50 and provides signals to the pneumatic...panel 36 to the cause of the error and the process is terminated.



The **ventilator** control system 10 provides two independent feedback paths to assure the clinician 16 that his...

...displays 60 a series of measurements (e.g., peak airway pressure, peak airway flow, and **PEEP** ) from the waveform data both numerically and graphically, Second, the display controller 12 displays 54...

...the embedded controller 14 and passed directly to the display 24. One feature of the **ventilator** control system 10 is that it can be configured to provide an assisted phase of...

...the accumulated volume of gas inhaled by the patient as a result of his spontaneous **respiratory** muscle activity can be monitored. To accomplish this 7th the sensor monitoring system 19 measures the...

...volume dynamically according to measured patient flow and pressure signals indicating the phase of the **respiratory** cycle.

In particular, the embedded controller 14 may increase the trigger volume set by the...

...system 4 1, and not by spontaneous efforts of the patient.

Another feature of the **ventilator** control system is its ability to distinguish between active inspiratory effort and passive reverse airflow ...measured until the trigger volume has been reached (Steps 320, 330).

Another feature of the **ventilator** control system is its ability to compensate for gas flow resistance into and out of...  
...input device 26, the clinician 16 can set a resistance parameter of the patient's **respiratory** system to a selected value. Alternatively, the display controller 12 may calculate a value for...

...row of touch sensitive on/off buttons 66 includes: a Power button that controls the **ventilator** control system- a Freeze button to pause the display- a Modes button to display various...

...play back a database of historical patient protocols; a 100% O<sub>2</sub> button to flush the **ventilator** with oxygen; Help and Save buttons; and ... other capabilities.

The left side of the screen includes a list of the publically available **ventilator** control settings. The top area displays the current mode of ventilation 67 (e.g., Backup...and partially controlled by the patient, and mandatory breaths, those triggered and controlled by the **ventilator** . The ratio of the colored areas indicates the ratio of spontaneous to mandatory breathing during...

...When the clinician selects a phase of a waveform, the display controller displays the associated **ventilator** controls for available for adjustment by the clinician. The display controller provides cursors 201 which waveform values, positioning based on **user interface** gestures.

The background of the waveform (74, 76) includes color shading to indicate breath phase...

...and scale information. Redrawing these graphics as new waveform samples are displayed generally requires substantial **computer** time, and the display controller performs this function efficiently notwithstanding the

complexity of the background...Inspiratory Pressure 2 to 120 cmH<sub>2</sub>O  
 Exhalation Assist 0 to 30 cmH<sub>2</sub>O/L/sec  
 PEEP 0 to 20 cmH<sub>2</sub>O  
 Inspiratory Time 0.2 to 4 sec  
 Inspiratory Pause Time 0...

...L/min  
 Oxygen Percentage 21 to 100%  
 Peak Inspiratory Pressure 0 to 120 cm.H<sub>2</sub>O  
 PEEP 0 to 20 cmH,<sub>2</sub>O  
 Mean Airway Pressure 0 to 120 cmH<sub>2</sub>O  
 Inspiratory Time 0...

...and Indicators  
 I-Egh/Low Exhaled Tidal Volume Alarm 50 to 2000 ml,  
 FEgh/Low **Respiratory** Rate Alarm 2 to 150 bpm  
 Low Oxygen Fresh Gas Flow Automatic, % 02  
 depend  
 Low...Embedded Controller - Referring again to Fig. 1, the embedded controller electronics 14 is based around **microprocessors** 31, 32. The **microprocessor** 32 is in electrical communication-with the **ventilatory** unit 17 and the **microprocessor** 31 is in electrical communication with the sensor monitoring system 19. The embedded controller relies...

...custom printed circuit boards to perform other functions. The modules, the printed circuit boards, the **ventilatory** unit pressure processors 32 and the airway processor 31 are mounted on or connected to...

...and provides battery backup for a average of one hour.

The embedded controller 14 has **microprocessor** and associated input/output hardware to provide for closed loop control of pneumatic system 41...Third Gas.

The embedded controller 14 communicates with the display controller 12 via a shared **memory** interface 15 at a data transmission rate exceeding 1000 bytes per second.

4. Data...

...to FIGS. 1 and 11, the figures illustrate the data structure hierarchy for the **ventilator** control system. Using an input device 26 such as the touch-sensitive display 24 within...

...13. In any case, the clinician 16 sends the new therapy control structure to the **memory** for use by the embedded controller 14 in controlling the pneumatic system 41. A control) is defined as a collection of **ventilator** control settings 154 and an array of waveform samples 156. Phase definitions and requirements for...

...to measurable system performance, and correlate closely to published descriptions of the desired behavior of **mechanical ventilators**.

More specifically, the therapy control structure 140 is a nested hierarchy of increasingly complex control...

...control, which occurs within therapy control, which is the clinically specified therapy that drives the **ventilator** pneumatic system 41. Once each cycle, ventilation control moves from one control state to assist phase to a **PEEP** phase, but these phases may be further subdivided for a finer granularity of control.

After...

...Within a phase, within a breath, within a mode, within a therapy, there is a **ventilator** control setting structure 154. This structure contains an array of samples that comprise a specified...

...is driven by the waveform sample specific for the cycle, and by a collection of **ventilator** control settings 154 specific for the phase. The cycle time is in milliseconds, and is...

...therapy may be specified by the clinician and take control at the next cycle.

Each **ventilator** control setting structure 158 contains necessary and sufficient information to control one parameter of ventilation...

...adjusted automatically within the specified range. Each phase control structure has its own collection of **ventilator** control settings, although in practice, phases within a breath generally share the same collection.

The...

...of hazardous conditions by permitting non-programmers to review and understand the function of the **ventilator** control system.

Several breath control structures are predefined in the embedded controller. These breath control relating to airway resistance or negative pressure in the **ventilatory** unit (Step 1). These values are then compared with data relating to airway - 24 resistance or negative pressure in the **ventilatory** unit that have been measured or calculated by the **data processing unit** (Step 2). It is then determined whether these sets of data are equal to each...

...7). It is then determined whether airway pressure is greater than zero and less than **PEEP** (Step 8). If airway pressure is greater than zero and less than **PEEP**, airway resistance is calculated and pressure in the **ventilatory** unit is measured (Step 9). After these measurements and calculations are made, the cycle recommences (Step 2). If airway 5 pressure is not greater than zero and less than **PEEP**, it is determined whether the alarm has been overridden (Step 10). If the alarm has...

...status of the patient's pulmonary system. The simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 in response to the set of breath parameters and the response of...

...is unaffected.

- 25 When the clinician 16 begins changing settings in the simulation mode, the **ventilator** control system 10 predicts the effects of the change and displays the predicted result on the display 24. The simulator 212 uses a standard two parameter model of a **respiratory** system and the current calculated values of the patient's resistance and compliance to predict the effect. The model assumes no contribution from the patient's **respiratory** muscles (i.e., a passive inspiration and exhalation cycle). The model used is.

Airway Pressure...

...Compliance)

+ (Airway Flow x Airway Resistance).

I O A change in patient intervention in current **ventilators** typically requires multiple setting changes. Implementing such setting changes is greatly complicated by the series...

...background. Other controls are listed as active or inactive. The explicit list of active controls **clearly** delineates the exact **function** of the mode and alleviates confusion caused by inconsistent or incomplete definitions. Moreover, the simulator 212 can precisely replicate the behavior of modes on preexisting **ventilators**.

The clinician 16 can make adjustments to the list of controls to accurately simulate the **ventilator** that a hospital's staff has been trained to use. The list of controls together...

...simulated behavior can help teach the effects of various modes on patients, rather than the **ventilator** -specific mode definition.

As claimed in FIG. 13, while the simulator 212 predicts the shape...a touch zone on the display 24. The processor 22 copies the selected patient protocol into **memory**. In the operational mode, the processor 22 instructs the embedded controller 14 1 5 to...

...selected patient protocol. In the simulation mode, the simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 and the resulting response of the patient's pulmonary system.

The processor...

...expected.

FIG. 14 is a detailed functional block diagram of the simulator feature of the **ventilator** control system 2 1 0. The clinician manipulates a control setting slider 216 to 3 0 change or set a **ventilator** control setting. The clinician's input are stored in a **memory** - 27 218. The simulator 220 receives the inputs and creates a phase control structure, a...

...a therapy control structure) is transmitted to the embedded controller (at 224) via the shared **memory** interface. The embedded controller validates the settings within the breath control structure 226. The processor...data stream can be generated by sensors, which is the usual manner in which the **ventilator** operates, by the simulator 212 which uses the breath parameters and measured patient parameters to...

...to display real data, simulated data and epoch data is an important feature of the **ventilator** control system.

- 28 9. Integrated Control/Data/Alarm Display - Referring again to FIG. 7, patient...selected targets appropriate for the range, and which, if enabled, 1 5 means that the **ventilator** control system will seek to accomplish a range target goal 213 by varying the control...the trigger for the transition from variable pressure support (VPS) to assist control (A/C **pc**) is minute volume (MV), while the trigger for the - 30 transition from assist control to...

...the patient, with much more power and flexibility than selecting from a set of simple **ventilator** modes preset by the manufacturer.

Equivalents

1 5 While the invention has been particularly shown...

Claim

- I 1. A method of compensating for the gas flow resistance in a **ventilatory apparatus**, the method comprising the steps of:  
determining the peak exhalation flow rate;  
determining the airway...  
...exhalation circuit such that the effective circuit pressure is greater than zero and less than **PEEP**.
- 2 A method of claim 1, further comprising adjusting the amount of negative pressure to generate a predetermined effective circuit pressure with a measured value between zero and **PEEP**.
- 3 A method of claim I further comprising measuring an exhaled tidal volume and adjusting...
- ...said instantaneous changes  
with predetermined parameters; and  
storing these data in a database.
- 5 A **ventilator assist device** comprising:  
a reservoir for inhaled and exhaled gas in communication with a **breathing apparatus** adapted for attachment to a patient'.  
a source of negative pressure in communication with said reservoir;  
- 32 a **data processing unit** in electrical communication with said negative pressure source and also in electrical communication with an...  
...circuit resistance sensor; said exhalation flowmeter and said circuit resistance sensor in communication with said **breathing apparatus**;  
and a **user interface** in electrical communication with said negative pressure source allowing direct setting of a value for desired negative airway pressure by a user.
- 6 The **ventilator assist device** of claim 5 further comprising:  
a flexible canister attached to gas inflow and outflow circuits of a **ventilator** in pneumatic communication with the exhalation circuit adapted for connection to the patient being ventilated...2 1 generated in said airway tubing that is greater than zero and less than **PEEP**.
- 7 The controlling processor of claim 6 further comprising:  
a first data processor in electrical...  
...applied to generate a pressure in said airway tubing greater than zero and less than **PEEP**;  
said third data processor further calculating from the data input from said exhalation flowmeter and...
- ...first, second and third data processors, 1 5 wherein said database is adapted for storing **data processed** by said first, second and third data processors.
- 8 The **user interface** of claim 5 further comprising:  
a display screen and the control panel, whereby said display...  
...controls;  
said plurality of controls in electrical communication with the gas flow controller; and said **user interface** in electrical communication with the database, with the third data processor and with the gas...

...comprising:

an alarm system in electrical communication with the third data processor and with the **user interface** that is triggered by a level of pressure in said airway tubing less than zero or greater than **PEEP** ; and  
an override device in electrical communication with said alarm system and with said **user interface** that discontinues the alarm signal in response to a command input by the user. I...

Set	Items	Description
S1	147107	(VENTILAT? OR RESPIRAT? OR BREATH?) (3N) (DEVICE? OR UTENSIL? OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN- C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2	1897400	VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR HFV OR IMV OR IPAP OR CPAP OR PEEP OR CPAP
S3	7895338	CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE- T? OR OVERRID? OR OVERWRT? OR OVER() (RIDE? OR RIDING OR WRIT- ?) OR REPROGRAM? OR REMOV? OR RESET? OR MODIF?
S4	16190876	OPERAT? OR FUNCTION?
S5	5459410	PERFORMANC? OR WORKING? OR EXECUTI?
S6	14535756	DATA? OR PROGRAM?
S7	859354	RUN OR RUNS OR RUNNING OR RAN
S8	103624	(READ? OR SCAN? OR DECOD?) (5N) (WRIT? OR CODE? OR CODING? OR CODIF?)
S9	30904	(CHIP? OR SMART? OR DEBIT? OR PROGRAMABL? OR PROGRAMMABL? - OR MEMORY) (3N) CARD? OR SMARTCARD? OR CHIPCARD?
S10	291441	(STORE? OR STORING? OR STORAGE) (3N) (DEVICE? OR MEDIUM? OR - ELECTRONIC? OR OPTIC? OR MAGNET?) OR USER?() INTERFACE?
S11	1035207	CACHE? OR MEMORY? OR RAM OR (EXTERNAL OR REMOVABL? OR DETA- CHABL? OR STANDALONE OR STAND() ALONE OR PORTABL OR INSERTABL?- ) (2N) (UNIT? OR DEVICE?)
S12	1050617	CPU OR CPUS OR PROGRAM?() CONTROL? OR PROCESS? (2N) CONTROL? - OR MICROPROCESS? OR DATAPROCESS? OR CENTRALPROCESS? OR (MICRO OR DATA OR CENTRAL) () PROCESS?
S13	376672	PROCESS?() UNIT? OR WORKSTATION? OR WORK() STATION? OR DESKT- OP? OR DESK() (TOP OR TOPS) OR SERVER?
S14	5992536	COMPUTER OR COMPUTERS OR PC OR PCS
S15	18204098	METHOD? ?
S16	712	S1:S2 AND S9:S11 AND S12:S14
S17	16	S16 AND S3 (5N) (S4:S14)
S18	94	S16 AND S3
S19	94	S17:S18
S20	33	S19 AND S15
S21	94	S19:S20
S22	72	RD (unique items)

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Set	Items	Description
S1	29830	(VENTILAT? OR RESPIRAT? OR BREATH?) (3N) (DEVICE? OR UTENSIL? OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN- C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2	179677	VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR HFV OR IMV OR IPAP OR CPAP OR PEEP OR CPAP
S3	4825840	CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE- T? OR OVERRID? OR OVERWIT? OR OVER() (RIDE? OR RIDING OR WRIT- ?) OR REPROGRAM? OR REMOV? OR RESET? OR MODIF?
S4	11998556	OPERAT? OR FUNCTION?
S5	10535414	PERFORMANC? OR WORKING? OR EXECUTI?
S6	12453413	DATA? OR PROGRAM?
S7	4094086	RUN OR RUNS OR RUNNING OR RAN
S8	212009	(READ? OR SCAN? OR DECOD?) (5N) (WRIT? OR CODE? OR CODING? OR CODIF?)
S9	246586	(CHIP? OR SMART? OR DEBIT? OR PROGRAMABL? OR PROGRAMMABL? - OR MEMORY) (3N) CARD? OR SMARTCARD? OR CHIPCARD?
S10	553829	(STORE? OR STORING? OR STORAGE) (3N) (DEVICE? OR MEDIUM? OR - ELECTRONIC? OR OPTIC? OR MAGNET?) OR USER?() INTERFACE?
S11	1164476	CACHE? OR MEMORY? OR RAM OR (EXTERNAL OR REMOVABL? OR DETA- CHABL? OR STANDALONE OR STAND() ALONE OR PORTABL OR INSERTABL? - ) (2N) (UNIT? OR DEVICE?)
S12	1002468	CPU OR CPUS OR PROGRAM?() CONTROL? OR PROCESS? (2N) CONTROL? - OR MICROPROCESS? OR DATAPROCESS? OR CENTRALPROCESS? OR (MICRO OR DATA OR CENTRAL) () PROCESS?
S13	2320080	PROCESS?() UNIT? OR WORKSTATION? OR WORK() STATION? OR DESKT- OP? OR DESK() (TOP OR TOPS) OR SERVER?
S14	6925033	COMPUTER OR COMPUTERS OR PC OR PCS
S15	1693714	METHOD? ?
S16	5051036	PROCESS??
S17	1865108	PROCEDUR?
S18	2776819	MODE? ?
S19	3225	S1:S2 AND S9:S11 AND S12:S14
S20	587	S19 AND S3(5N)S4:S14
S21	39	S20 AND S1:S2(5N)S9:S14
S22	28	RD (unique items)

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